ORAL ARGUMENT SCHEDULED FOR JANUARY 20, 2026

No. 24-1193
(consolidated with Nos. 24-1261, 24-1266, 24-1271, 24-1272)

In the United States Court of Appeals For the District of Columbia

CHAMBER OF COMMERCE OF THE
UNITED STATES OF AMERICA et al.,
Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY AND LEE M. ZELDIN,
IN HIS OFFICIAL CAPACITY AS ADMINISTRATOR, UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY,
Respondents, and

CLEAN CAPE FEAR, et al.,
Respondent-Intervenors

On Petition for Review of Final Action by the United
States Environmental Protection Agency –
89 Fed. Reg. 39,124 (May 8, 2024)

DEFERRED JOINT APPENDIX
VOLUME 1 OF 2

(Names and addresses of counsel appear inside cover)

Andrew R. Varcoe
Stephanie A. Maloney
U.S. CHAMBER LITIGATION CENTER
1615 H Street, NW
Washington, DC 20062
(202) 463-5337
avarcoe@USChamber.com
smaloney@USChamber.com

Counsel for Petitioner Chamber of Commerce of the United States of America

Leah Pilconis
ASSOCIATED GENERAL CONTRACTORS OF AMERICA, INC.
2111 Wilson Blvd., Suite 1000
Arlington, VA 22201
(703) 837-5332
Leah.pilconis@agc.org

Counsel for Petitioner Associated General Contractors of America, Inc.

Elbert Lin
Counsel of Record
David M. Parker
Paul T. Nyffeler
HUNTON ANDREWS KURTH LLP
Riverfront Plaza, East Tower
951 East Byrd Street
Richmond, VA 23219-4074
(804) 788-8200
elin@huntonAK.com
dparker@huntonAK.com
pnyffeler@huntonAK.com

Matthew Z. Leopold
HOLLAND & KNIGHT LLP
800 17th St. NW,
Washington, DC 20006
(202) 955-3000
mleopold@hklaw.com

Counsel for Petitioners Chamber of Commerce of the United States of America, Associated General Contractors of America, Inc., National Waste & Recycling Association, and American Chemistry Council

Aleacia Chinkhota
AMERICAN CHEMISTRY COUNCIL
Assistant General Counsel, Legal Services
700 2nd Street, NE
Washington, DC 20002
202-249-6131
Aleacia_Chinkhota@americanchemistry.com

Counsel for Petitioner American Chemistry Council

Christopher L. Bell
D.C. Bar # 412857
GREENBERG TRAURIG, LLP
1000 Louisiana Street, Suite 6700
Houston, TX 77002
(713) 374-3556
bellc@gtlaw.com

Counsel for Petitioner Institute of Scrap Recycling Industries, Inc., d/b/a Recycled Materials Association

Susan Parker Bodine
EARTH & WATER LAW LLC
1455 Pennsylvania Ave., NW
Suite 400
Washington, DC 20004
(202) 658-8340
susan.bodine@earthandwatergroup.com

Counsel for Petitioner American Forest & Paper Association

Heather Lyons
General Counsel
RECYCLED MATERIALS ASSOCIATION
1250 H Street NW, Suite 400
Washington, DC 20005
(202) 662-8500
hlyons@recycledmaterials.org

Richard S. Moskowitz
Tyler Kubik
AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS
1800 M Street, NW
Suite 900 North
Washington, DC 20036
(202) 457-0480 (telephone)
(202) 457-0486 (facsimile)
rmoskowitz@afpm.org
tkubik@afpm.org

Brittany Pemberton
BRACEWELL LLP
2001 M St. NW
Washington, DC 20036
(202) 828-1708 (telephone)
(800) 404-3970 (facsimile)
brittany.pemberton@bracewell.com

Counsel for Petitioner American Fuel & Petrochemical Manufacturers

Jonathan Kalmuss-Katz
EARTHJUSTICE
48 Wall Street, Floor 15
New York, New York 10005
(212) 823-4989
jkalmusskatz@earthjustice.org

Lillian Zhou
Alana Reynolds
1001 G St NW, Suite 1000
Washington, DC 20001
(202) 667-4500
lzhou@earthjustice.org
areynolds@earthjustice.org

Counsel for Respondent-Intervenors Clean Cape Fear, Environmental Justice Task Force, Fight for Zero, Merrimack Citizens for Clean Water, and Natural Resources Defense Council

Jin Hyung Lee
Environmental Defense Section
Environment & Natural Resources Division
U.S. DEPARTMENT OF JUSTICE
P.O. Box 7611
Washington, DC 20044
(202) 598-7264
Jin.hyung.lee@usdoj.gov

Counsel for Respondents

TABLE OF CONTENTS

VOLUME 1 of 2

ACTIONS UNDER REVIEW

INDEXED RECORD MATERIAL

VOLUME 2 of 2

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–OLEM–2019–0341; FRL–7204–03–OLEM]

RIN 2050–AH09

Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA'' or ''Superfund''), the Environmental Protection Agency (EPA) is designating two per- and polyfluoroalkyl substances (PFAS)—perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers—as hazardous substances. The Agency reached this decision after evaluating the available scientific and technical information about PFOA and PFOS and determining that they may present a substantial danger to the public health or welfare or the environment when released. The Agency also determined that designation is warranted based on a totality of the circumstances analysis, including an analysis of the advantages and disadvantages of designation.

DATES: Effective July 8, 2024.

ADDRESSES: EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OLEM–2019–0341. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. With the exception of such material, publicly available docket materials are available electronically in *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, Office of Emergency Management (5104A), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–8019; email address: *jacob.sicy@epa.gov* or Linda Strauss, Office of Superfund Remediation and Technology Innovation, Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0797; email address: *strauss.linda@epa.gov.*

SUPPLEMENTARY INFORMATION: *Acronyms and Abbreviations:* We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of the preamble and for reference purposes, EPA defines the following terms and acronyms here:

AFFF Aqueous film-forming foam
ARARs Applicable or Relevant and Appropriate Requirements
ATSDR Agency for Toxic Substances and Disease Registry
CDC Centers for Disease Control and Prevention
CASRN Chemical Abstracts Service Registry Number
COC Contaminant of Concern
CDR Chemical Data Reporting
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
CFR Code of Federal Regulations
DoD Department of Defense
DOE Department of Energy
EA Economic Analysis
ECF Electrochemical fluorination
EJ Environmental justice
EPA Environmental Protection Agency
EPCRA Emergency Planning and Community Right-to-Know Act
EU European Union
FAA Federal Aviation Administration
FDA Food and Drug Administration
FR Federal Register
ICR Information Collection Request
LEPC Local Emergency Planning Committee
MCL Maximum contaminant level
MCLG Maximum Contaminant Level Goals (MCLGs)
NAICS North American Industrial Classification System
NCP National Oil and Hazardous Substances Pollution Contingency Plan
NECI National Enforcement Compliance Initiative
NHANES National Health and Nutrition Examination Survey
NPDWR National Primary Drinking Water Regulation
NPL National Priorities List
NRC National Response Center
OMB Office of Management and Budget
PCBs Polychlorinated biphenyls
PFAS Per- and polyfluoroalkyl substances
PFOA Perfluorooctanoic acid
PFOS Perfluorooctanesulfonic acid
PFOSA Perfluorooctanesulfonamide
PHGs Public health goals
ppt parts per trillion
PRG Preliminary remediation goal
PRP Potentially responsible party
PRSC Post-Removal Site Control
PWS Public water system
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
RfD Reference dose
RQ Reportable quantity
SAB Science Advisory Board
SDWA Safe Drinking Water Act
SERC State Emergency Response Commission
SNURs Significant New Use Rules
TEPC Tribal Emergency Planning Committee
TERC Tribal Emergency Response Commission
TRI Toxic Release Inventory
TSCA Toxic Substances Control Act
UCMR Unregulated Contaminant Monitoring Rule
UMRA Unfunded Mandates Reform Act
U.S. United States
WWTP Wastewater treatment plant

Table of Contents

I. Executive Summary

A. Overview

Pursuant to section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), EPA is designating perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers, as hazardous substances.[1] Each of the actions adding PFOA, PFOS, and their salts and structural isomers, to CERCLA's hazardous substances list is independent, and severable from the others. The Agency evaluated the available scientific and technical information about those substances and concluded that designation of each substance is warranted under the criteria in section 102(a) because both PFOA and PFOS, and their salts and isomers, may present substantial danger to public health or welfare or the environment. Exercising its discretion with respect to when to make a finding under section 102(a), EPA as part of its decision-making process went beyond considering whether PFOA and PFOS ''may present a substantial danger to public health welfare or the environment'' within the meaning of section 102(a), and also performed an additional analysis that weighed the advantages and disadvantages of designation, including quantitative and qualitative benefits and costs. As part of that additional discretionary analysis, EPA determined that the advantages of designation outweigh the disadvantages. Among other advantages, designation best serves CERCLA's two primary objectives—the timely cleanup of contaminated sites and holding polluters accountable for contamination they caused (*i.e.,* the ''Polluter Pays'' principle). Designation provides necessary tools to address the challenge of PFOA and PFOS contamination in the environment. Designation will allow EPA to utilize all CERCLA's authorities, which will enable EPA to address more sites, take earlier action, and to expedite eventual cleanup. Designating PFOA and PFOS as CERCLA hazardous substances is thus critical to addressing PFOA and PFOS releases in the environment and to protecting public health.

B. ''May Present Substantial Danger to Public Health or Welfare or the Environment''

EPA is taking final action on the proposed finding that both PFOA and PFOS ''may present substantial danger to public health or welfare or the environment'' when released into the environment after considering the available scientific and technical information and after considering comments on the proposed determination. Available information indicates that human exposure to PFOA and/or PFOS is linked to a broad range of adverse health effects, including developmental effects to fetuses during pregnancy or to infants (*e.g.,* low birth weight, accelerated puberty, skeletal variations), liver effects (*e.g.,* tissue damage), immune effects (*e.g.,* antibody production and immunity), and other effects (*e.g.,* cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk.

In addition, toxicity assessments in support of EPA's 2024 National Primary Drinking Water Regulation for PFAS (*2024a*) indicate that PFOA and PFOS may cause carcinogenic effects in humans and animals (*Barry et al., 2013; Bartell & Vieira, 2021; Goodrich et al., 2022; Shearer et al., 2021; Vieira et al., 2013*). In the final toxicity assessments, EPA assessed the weight of the evidence for the available cancer data and determined that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005, 2024b, 2024c, 2024d*). Additionally, in November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly

[1] PFOA and PFOS are part of a group of human-made chemicals known as per- and polyfluoroalkyl substances (PFAS). All references to PFOA and PFOS in this notice include their salts and structural isomers.

carcinogenic to humans (Group 2b) (Zahm, et al., 2023).

The potential for adverse health effects is exacerbated by the fact that PFOA and PFOS are persistent in the environment, which can cause long-term exposure. PFAS, including PFOA and PFOS, are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause them to be extremely resistant to degradation and to remain in the environment for long periods of time. This means that the potential for human exposure continues long after an immediate release has ended. PFOA and PFOS are also highly mobile in the environment and can migrate away from the point of initial release. Studies also show that PFOA and PFOS persist in humans and animals (*i.e.,* bioaccumulate) with estimated elimination half-lives [2] in humans ranging from about two to three years for PFOA to four or five years for PFOS [3] (*ATSDR, 2021*). Because PFOA and PFOS can remain in the human body for these long durations, individuals who have consistent ongoing exposures to elevated concentrations of PFOA and PFOS (*e.g.,* individuals exposed by drinking contaminated well water) can have elevated concentrations of these compounds in their bodies which may contribute to adverse health effects (Hall et al., 2023; Hoffman et al., 2011; Kotlarz et al., 2020; Steenland et al., 2009).

PFOA and PFOS are prevalent in the environment and can be found in surface water, groundwater, soil, and air. PFOA and PFOS are prevalent because they have been produced and used since the 1940s, were among the most widely used of the PFAS constituents and persist in the environment for a long time. PFOA and PFOS have historically been used in a wide range of consumer products including carpets, clothing, fabrics for furniture, packaging for food and cookware, and firefighting foam, in addition to being used in a wide range of industrial processes. *See* Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 FR 54415, 54417 (proposed Sept. 6, 2022) (hereinafter ''Proposed Rule'' or ''Proposal'') (providing a brief history of PFOA and PFOS production and use). Domestic production and import of PFOA has been phased out by the companies participating in the 2010/2015 PFOA Stewardship Program (*U.S. EPA, 2023c*). Some uses of PFOS are ongoing. The sustained and broad use of PFOA and PFOS by industries means that many sites may be contaminated with high levels of PFOA and PFOS. Furthermore, these substances may still be released into the environment through use and disposal of legacy products and through limited ongoing uses.

PFOA and PFOS have been detected in the drinking water of millions of Americans and are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States (*ATSDR, 2021; Cadwallader et al., 2022; U.S. EPA, 2017, 2024a*). This exposure potential is exacerbated by their persistence and mobility in the environment (*Langenbach & Wilson, 2021*). The prevalence of PFOA and PFOS is further demonstrated by the fact that these chemicals were detected in the blood of nearly all of the participants in the latest U.S. Centers for Disease Control and Prevention's (CDC) National Health and Nutrition Examination Survey (NHANES) for which data is available from 2017–2018. (*CDC, 2022*). This information indicates widespread though generally declining exposure to PFOA and PFOS in the U.S. population. From 1999–2000 to 2017–2018, blood PFOS levels declined by more than 85%. From 1999–2000 to 2017–2018, blood PFOA levels declined by more than 70%. While serum concentrations of PFOA and PFOS in the general population are declining, there is evidence that PFOA and PFOS releases continue to result in elevated environmental concentrations and the potential for human exposure. For example, under the 2018–2019 National Rivers and Streams Assessment (NRSA) PFOS was detected in 91% of the 290 fish fillet composite samples analyzed, corresponding to PFOS being detected in 92% of the sampled population of 41,099 river miles (a statistically significant decrease of 6.7% from NRSA 2013–14) (U.S. EPA, 2023i).

In consideration of the evidence of adverse effects to human health and the environment from PFOA and PFOS exposure, their persistence and mobility in the environment, and the significant potential for human exposure due to their prevalence in the environment, EPA concludes that PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released into the environment. EPA further finds that populations located near highly contaminated sites are of particular concern because they are at risk of a disproportionately high potential of repeat exposure to PFOA and PFOS as compared to the general population and across demographic characteristics and repeated exposures increase the likelihood of adverse health effects, as discussed further in the Preamble, Section VI.A,2. d. For these reasons, designation of PFOA and PFOS as hazardous substances is warranted.

C. ''Totality of the Circumstances'' Analysis

Along with concluding that PFOA and PFOS each, when released, ''may present a substantial danger'' to public health or welfare or the environment and therefore meet the statutory designation criteria, EPA also exercised discretion to conduct an additional totality of the circumstances analysis. The analysis looks to CERCLA section 102(a), and its broader context, to help identify the information to weigh and how to balance multiple considerations. In conducting the analysis as to PFOA and PFOS, EPA identified and weighed the advantages and disadvantages of designation relative to CERCLA's purpose alongside the formal benefit-cost analysis, including quantitative and qualitative benefits and costs, provided in the Regulatory Impact Analysis [4] accompanying this final rule. That ''totality of the circumstances'' analysis confirmed EPA's conclusion that designation is warranted because the advantages of designation outweigh the disadvantages.

EPA considered how designation supports CERCLA's primary objectives to clean up contaminated sites and ensure the ''Polluter Pays.'' EPA concluded that designation best serves those objectives and that CERCLA is the best tool to address the legacy of sites contaminated with these substances and to address additional releases of these chemicals in the future. EPA considered that designation would allow EPA to deploy the full suite of CERCLA tools to identify, characterize, and clean up the most contaminated sites expeditiously. It allows EPA to ensure that those parties responsible for significant

[2] Elimination half-life is the length of time required for the concentration of a particular substance to decrease to half of its starting dose in the body.

[3] Data from two studies in Table 3–5 of ATSDR 2021 (Seals et al., 2011 and Zang et al., 2013) were not included in EPA's estimate of elimination half-life because their findings were significantly different for the other studies, and may not be the most representative.

[4] The RIA was conducted in a consistent manner with economic principles and governmental guidance documents for economic analysis (*e.g.,* OMB Circular A–4 and EPA's Guidelines for Preparing Economic Analyses) and summarized monetized costs and benefits. The RIA is a neutral analysis tool that allows the federal government to consider potential benefits and costs that may result from designation. It does not consider whether designation is warranted.

contamination bear the costs of cleaning it up. The use of these authorities will allow EPA to address more sites and to do so earlier in time than it otherwise could in the absence of designation. The ability to address more contaminated sites will provide meaningful health benefits to the communities near these sites by reducing the risk of exposure and the potential adverse health and environmental effects associated with such exposure. EPA expects these cleanups will have meaningful health benefits similar to health benefits typically associated with CERCLA actions. EPA also considered the potential quantifiable and qualitative costs and benefits of designation and the comments expressing concerns about widespread liability and litigation after designation. As explained below, EPA finds that the advantages of designation outweigh the disadvantages and that designation is warranted.

EPA's totality of the circumstances analysis considered the adverse health impacts and environmental challenges posed by PFOA and PFOS contamination. PFAS, including PFOA and PFOS, are a nationwide concern because exposure to these chemicals is linked to significant adverse human health impacts, they were in wide use, and they persist and are mobile once released into the environment. CERCLA provides the tools for addressing such contamination and provides a framework to allow EPA, and other delegated Federal agencies,[5] to make site-specific determinations and response decisions to address instances of PFOA and PFOS releases that pose unacceptable risk. Specifically, CERCLA provides authority to respond to releases of hazardous substances (including legacy releases). CERCLA's cleanup process is comprehensive in that it can address contamination to air, water, groundwater, and soil. EPA's CERCLA response authority also extends from initial investigations to cleanup. No other statute that EPA administers provides the breadth of authority to fully address highly contaminated sites. Thus, CERCLA is the best authority to address existing contamination to mitigate the disproportionate risk borne by communities impacted by those sites. Furthermore, CERCLA is a liability statute. The CERCLA cost recovery and enforcement provisions ensure that those parties responsible for significant contamination can be held accountable to pay for or conduct clean up. Designation is the best way for EPA to effectuate CERCLA's objectives with respect to releases of PFOA and PFOS.

EPA also considered whether designation is warranted considering EPA's existing CERCLA authority, which allows the Agency to address PFOA and PFOS as ''pollutants or contaminants.'' CERCLA's authority to address pollutants or contaminants is much more circumscribed than the authority to address hazardous substances. Specifically, CERCLA's notification requirements for releases do not attach to pollutants or contaminants; EPA cannot address a release of pollutants or contaminants unless the Agency demonstrates that the release may present an ''imminent and substantial danger''; CERCLA does not provide cost recovery authority for actions taken solely in response to releases or threats of releases of pollutants or contaminants; and CERCLA authority to compel potentially responsible parties (PRPs) to conduct or pay for response work does not extend to pollutants or contaminants. Designating PFOA and PFOS as CERCLA hazardous substances eliminates those limitations. Elimination of those limitations provides meaningful advantages.

EPA also considered the advantages of designation. The most significant direct costs associated with designation stem from the requirement for facilities to report releases of PFOA and PFOS that occur after designation. EPA determined these costs were fairly minimal and reasonable in light of the benefits of release notifications. Notification ensures transparency about new releases of PFOA and PFOS, and it allows EPA and affected States and communities to immediately evaluate a release and quickly respond, as necessary, to address risks to human health or the environment. Without notice, EPA is less able to obtain key information to help protect affected communities. Thus, the notification requirement is an advantage that is necessary to adequately protect the public from future releases. Designation also allows EPA to streamline the Federal government's response authority to address releases of PFOA and PFOS, which will allow EPA to take action sooner. EPA can also begin the lengthy process of identifying, characterizing, and cleaning up the most contaminated sites without delay, either through enforcement or EPA-funded action.

Another key advantage to designation is that it best effectuates the Polluter Pays principle underpinning CERCLA. Designation improves equities by transferring costs of cleaning up PFOA and PFOS from the Superfund (''the Fund''),[6] which has been historically funded by taxpayer dollars, to those responsible for contamination. Absent designation, costs incurred for addressing PFOA and PFOS as pollutants or contaminants are paid for by the Fund, rather than responsible parties. Preservation of the Superfund is critical because the monies in it are insufficient to clean up all the existing contamination across the country from the more than 800 CERCLA hazardous substances as well as additional/emerging pollutants and contaminants. The ability to require PRPs to pay for PFOA and PFOS response costs means that more money will be available in the Fund to address a multitude of priorities, particularly at those sites where there is no viable PRP. It also allows EPA to address more releases earlier than it otherwise could absent designation. Further, cleanup to address PFOA/PFOS supported by designation may allow for incidental cleanup of co-contaminants, including other types of PFAS, which would also benefit human and environmental health. Because contaminated sites often have multiple contaminants of concern (''COCs''), the benefits from addressing co-contaminants may be substantial for some sites to the extent this occurs. It is critical to initiate more CERCLA actions to address PFOA and PFOS contamination now because the process from investigations to cleanups can take many years, if not decades. And, because PFOA and PFOS are persistent in the environment and highly mobile, further delay increases the extent of contamination, potentially increasing the number of individuals exposed to these substances, and also potentially increasing costs associated with cleanup.

EPA's ability to address PFOA and PFOS contamination through enforcement *and* EPA-funded action means more communities will be protected from disproportionate and unacceptable health risks, including communities with environmental justice

[5] Executive Order 12580 (Jan. 23, 1987, as amended) delegates CERCLA response authority to EPA, as well as the Secretaries of Defense, Interior, Agriculture, Commerce, and Energy with respect to releases from a facility or vessel under their jurisdiction, custody or control and to the U.S. Coast Guard with respect to releases involving the coastal zone, Great Lakes waters, ports, and harbors.

[6] Congress established the Hazardous Substances Trust Fund, otherwise known as the Superfund, to provide funding to address contamination. CERCLA also established liability for parties that contributed to releases of hazardous substances, CERCLA section 107(a), which allows EPA to shift costs from the Fund to PRPs.

(EJ) concerns. Published literature [7] supports the conclusion that certain communities with EJ concerns have a higher likelihood of exposure to PFAS, including PFOA/PFOS. For more information, see RIA Section 6.3 *Impacts on Communities with EJ concerns: Analysis.* Cleaning up more sites with PFOA and PFOS contamination will help to decrease their exposure to PFOA and PFOS, thus reducing their risk of detrimental health effects, such as decreased immune response to vaccination, decreased birthweight, increased total cholesterol, and cancer. Cleaning up sites also promotes economic benefits, such as improved property values and making land available for reuse. Improving environmental quality can improve local economies by supporting local business, such as recreation companies or industries that rely on natural products like agriculture. Improved quality of natural resources can also contribute to ecosystem services.[8]

EPA also considered the quantitative and qualitative direct and indirect costs and benefits evaluated in the RIA as part of its totality of the circumstances analysis.[9] EPA recognizes that designation will lead to both direct and indirect costs. The only quantifiable direct cost associated with designation is the notification requirement, for releases of PFOA and PFOS at or above 1 pound within a 24-hour period. EPA estimates that the notification requirement will cost $2,658 per release and that the total cost of the notification requirement is not anticipated to exceed $1,630,000 per year.[10] Notification is critical to ensuring that new releases are identified, evaluated, and addressed to the extent necessary to protect human health and the environment. EPA considers both the individual and total notification costs to be generally reasonable because of the value notification provides to impacted communities and regulatory agencies. Notification can avoid delays in evaluation of a new release. This is particularly important for persistent and mobile substances like PFOA and PFOS because early evaluation can determine whether the release poses an unacceptable risk that requires a response before PFOA and PFOA migrate away from the release. Such migration without intervention can lead to an increase in both the scope of the contamination and the costs necessary to address any identifiable risks.

With respect to indirect costs, EPA considered the costs associated with responding to releases of PFOA and PFOS at contaminated sites and with responding to future releases, either through direct EPA action with cost recovery or through enforcement. As stated above, EPA considers the ability to use the full suite of CERCLA authorities—including cost recovery and enforcement—to be an advantage of the rule. Designation eliminates current barriers to timely cleanup of contaminated sites and enables EPA to pursue parties responsible for significant contamination, these are the parties that should bear the costs of cleaning it up. When parties responsible for contamination are required to bear the cost of cleanup, more resources are made available to address additional cleanups. For example, EPA can compel a PRP to take action to address PFOA and PFOS pursuant to CERCLA section 106(a), which will then allow EPA to use Superfund monies and human resources to address other releases at other sites. Further, every contaminated site that is addressed can reduce the disproportionate burden borne by some of the communities at risk of exposure to PFOA and PFOS from the contamination. EPA's totality of the circumstances analysis included an evaluation of the benefit-cost analysis in the RIA (including indirect costs) as well as additional qualitative considerations related to designation, such as how CERCLA functions.

EPA is required to take a measured approach in responding to contamination. For instance, CERCLA ensures that costs are considered when determining the remedy. In addition, EPA, as well as other Federal agencies, have resource constraints that require CERCLA response actions to be prioritized to address the most urgent and highest risks as specified by the National Priorities List (NPL). The NPL is the list of sites of national priority among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States and its territories. It is intended primarily to guide EPA in determining which sites warrant further investigation. Eligibility for the NPL includes identifying priority sites based upon relative risk or danger that may be posed to public health or welfare or the environment, considering the population, the hazard potential of the hazardous substances at issue, the potential for contamination of drinking water supplies, the potential for direct human contact, the potential for destruction of sensitive ecosystems, and the damages to natural resources that may affect the human food chain when determining priority. Thus, CERCLA provides EPA with the ability to identify the sites with the highest human health and environmental risks and address those sites first, and the costs of addressing contamination are considered relative to the risks the contamination poses before a remedy is selected. before a remedy is selected.

Between FY 2003 and FY 2022, only about four percent of all contaminated sites added to EPA's Active Site Inventory were placed on the NPL. Since 2013, EPA has, on average, added 11 sites [11] per year to the NPL, and EPA

[7] Northeastern University—The PFAS Project Lab, ''PFAS Contamination Is an Equity Issue, and President Trump's EPA Is Failing to Fix It'' October 31, 2019. Available at: *https://pfasproject.com/2019/10/31/pfas-contamination-is-an-equity-issue-and-president-trumps-epa-is-failing-to-fix-it/.*

Lee, Susan, Avinash Kar, and Dr. Anna Reade, *Dirty Water: Toxic ''Forever'' PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities.* Natural Resources Defense Council, New York. 2021. *https://www.nrdc.org/sites/default/files/dirty-water-pfas-ej-communities-report.pdf*

Stoiber, T., Evans, S., & Naidenko, O.V. (2020). Disposal of products and materials containing per- and polyfluoroalkyl substances (PFAS): A cyclical problem. *Chemosphere 260,* Accessed at: *https://doi.org/10.1016/j.chemosphere.2020.127659.*

[8] Ecosystem services produce the life-sustaining benefits we receive from nature—clean air and water, fertile soil for crop production, pollination, and flood control.

[9] The terms ''direct'' and ''indirect'' as used to describe potential impacts of this rule are based on established definitions used for analyses under the Regulatory Flexibility Act (RFA). EPA is aware that ''direct'' and ''indirect'' costs have distinct definitions for CERCLA purposes; those CERCLA-specific definitions were not used for estimating costs for the purpose of designation. Both EPA and SBA have applicable RFA guidance documents that were considered in developing this rule. For this rule, reporting requirements are direct effects because upon designation of PFOA and PFOS as hazardous substances, entities that release a reportable quantity within a 24-hour period are required to use established procedures to report the release immediately by telephone and provide a follow-up written report. Potential liability for response costs for addressing PFOA and PFOS releases or threatened releases is an indirect effect of designation. This is because CERCLA response actions are not required by this rule, and are discretionary and contingent upon a series of many site-specific determinations. See RIA Section 1.4 *Scope of Analysis* and RIA Section 6.2 *Small Entity Analysis* for more detail.

[10] The designation may also result in minimal costs to federal agencies associated with CERCLA section 120(h) notice requirements when selling or transferring federally owned real property where PFOA/PFOS may be present. Future federal property sales and transfers involving property where PFOA and/or PFOS may be present is unknowable and therefore such costs are unquantifiable.

[11] This estimate is based on data from EPA's SEMS database with respect to non-federal NPL sites. EPA determined that it was appropriate to assess the designation's impact with respect to non-federal NPL sites only, because federal sites are generally expected to address PFOA and PFOS in the absence of designation consistent with CERCLA section 104. As discussed in Chapter 2 of the RIA, federal sites are addressing PFAS in the baseline as authorized by CERCLA section 104 and corresponding Executive Orders, as required by the

does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule. Moreover, NPL listing does not trigger any immediate actions, liability, or requirements for the site.[12]

CERCLA ensures that the most significant releases that pose the most risks to human health and the environment are prioritized, and designation will allow EPA to ensure more sites are evaluated sooner, thereby protecting more communities from PFOA and PFOS contamination. In Chapter 5 of the Regulatory Impact Analysis (RIA) for this rulemaking, EPA presents quantified potential response costs[13] that may occur after designation despite the uncertainty of future response actions. Every site is unique and the extent of action necessary to mitigate risks depends on many factors, which leads to uncertainties regarding response activities and associated costs. Notwithstanding these uncertainties, EPA used existing data to estimate response costs for PFOA and PFOS. Specifically, EPA used response costs data for EPA-lead response actions, potential costs associated with cleanup methods and technologies available to address PFOA and PFOS, and information about conditions at contaminated sites. EPA then used that data to assess the incremental costs of cleanup associated with addressing PFOA/PFOS contamination. Data available to EPA demonstrates that PFOA and PFOS generally are not found in isolation; rather, those substances are typically co-located or commingled with other "contaminants of concern" that on their own support a remedy. The estimated incremental costs to address PFOS and/or PFOS releases at NPL sites are those that the Agency believes it would incur absent the designation, which can be transferred to viable, liable parties as a result of designation. As EPA's funds would then be used for additional fund-led efforts to address contamination not addressed under the baseline, there will be a net increase in spending on response activities. This ability to transfer costs enables EPA to investigate and clean up additional NPL sites to address potential risks posed by any of the more than 800 hazardous substances, including PFOA and PFOS. EPA estimated the potential transfer of response costs associated with NPL sites range from $10.3M to $51.7M per year (at a 2% discount rate), depending on the cost premium associated with the response work to address PFOA and/or PFOS in addition to other Contaminants of Concerns (COCs)[14] at a given NPL site. Because EPA would use these funds for additional fund-led efforts to address contamination not addressed under the baseline, the transfer of $10.3M to $51.7M would result in additional costs of this same amount. Additionally, indirect costs associated with potential enforcement actions that may result in additional response activities for PFOA and PFOS at non-NPL sites are estimated to range from $327,000 to $18,100,000 per year (at the 2% discount rate), depending on the type of response actions taken at a given site. See RIA *Section.*

5.1 Indirect Costs and Transfers

EPA expects response costs to address PFOA and PFOS to represent an incremental increase above the cost of addressing other substances at NPL sites because, more often than not, PFOA and PFOS are likely to be co-located with or commingled with other substances. EPA also expects that costs to address PFOA and PFOS will fall within typical response cost ranges for actions to address other hazardous substances. This is because many of the same response and cleanup methods available, as noted in the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024),*[15] to address other hazardous substances can be used to address PFOA and PFOS (*e.g.,* dig and haul for soil and granulated activated carbon for water). Moreover, EPA expects that response and cleanup costs may decrease over time as associated methods improve. Finally, by addressing PFOA and PFOS releases earlier, EPA can mitigate the spread of contamination, which likely mitigates the costs of an otherwise more wide-spread cleanup.

EPA also considered liability and litigation that may arise after designation. CERCLA is designed to ensure that those responsible for contamination pay to clean it up. For PRPs that have significantly contributed to contamination, imposing CERCLA liability is wholly consistent with CERCLA and necessary to address the public health threat posed by PFOA and PFOS. However, EPA also gave serious consideration to potential liability for parties that have not played a significant role in contamination. Those parties include entities that did not generate PFOA- or PFOS-contaminated materials. EPA evaluated CERCLA liability limitations, EPA's enforcement policies, settlement protections for settling and non-settling parties, and parameters for CERCLA lawsuits to resolve who should pay and how much. Those mechanisms, combined with decades of historical practice, show that CERCLA liability is not unlimited; enforcement is targeted; and parties' ability to recover costs from other PRPs is constrained.

Although CERCLA's liability structure is broad, both the statute and EPA enforcement discretion policies may constrain a party's ability to secure reimbursement of response costs.[16] CERCLA includes liability exemptions as well as affirmative defenses against liability. *See, e.g.,* CERCLA section 101(10), 107(b), (d), (k). Parties must incur response costs before they can recover those costs from other viable, liable parties. And parties must prove that response costs incurred are consistent with the National Contingency Plan, CERCLA's implementing regulations. *Id.* section 107(a)(4)(B). EPA's enforcement authorities and policies can serve as a deterrent for responsible parties to pursue entities that did not contribute

NDAA, and consistent with federal facilities agreements under CERCLA section 102(a). Therefore, EPA expects that federal sites will address PFOA and PFOS contamination in the absence of the final rule. With federal sites taking action to address PFAS in the baseline, indirect impacts of the final rule will likely be related to actions taken at non-federal sites. For additional context, since FY 2000 EPA has added 8 federal sites to the NPL.

[12] EPA considered the portion of non-federal NPL sites that may be impacted by designation depending on site-specific circumstances. Of final, proposed, or deleted non-federal NPL sites that have been tested for PFOA and/or PFOS, an estimated 33.1% of NPL sites have detectable levels of PFOA and/or PFOS. See Section 3.3 of the RIA for more details about this estimate. In evaluating the designation's impact non-federal NPL sites, this estimate is instructive and serves as a benchmark for assessing designation's potential impact to those sites. There are currently 5 sites where either PFOA or PFOS contributed to NPL listing.

[13] The term "response" may include actions including but not limited to: site assessment, investigation, remedial action, and removal action. See CERCLA section 101(25). For a description of details on the differences between remedial and removal actions and other response activities under CERCLA, please see Section 2.1 of the RIA.

[14] Contaminants of Concerns (COCs) are chemicals identified during in-depth site studies (Remedial Investigation/Feasibility Study) that need to be addressed by a cleanup action because they pose a potential threat to human health or the environment.

[15] *Interim PFAS Destruction and Disposal Guidance; Notice of Availability for Public Comment* was published in the **Federal Register** on April 16, 2024 (89 FR 26879) *https://www.govinfo.gov/content/pkg/FR-2024-04-16/pdf/2024-08064.pdf.*

[16] Other Federal agencies including DOD, DOE, USDA, and DOI have delegated CERCLA authority. EPA's policies apply only to EPA and its exercise of enforcement discretion. Please note that EPA's policies are not regulations and do not create new legal obligations or limit or expand obligations under any Federal, State, Tribal or local law.

significantly to contamination.[17] EPA has a well-proven track record of developing enforcement discretion policies that have been effective and well-received.[18] EPA's enforcement policies, such as its policy regarding de minimis or de micromis parties and innocent landowner policies, have proven to be useful tools in convincing responsible parties not to pursue entities covered by these enforcement discretion policies. Finally, the statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled to contribution protection—the ability to block third-party claims for matters addressed in the settlement. These liability limitations and mitigation tools are more fully discussion in Section VI.B.2. EPA concludes that designation is not expected to result in excessive litigation and that CERCLA will continue to operate as it has for decades. Indeed, CERCLA's liability framework, coupled with EPA enforcement policies, has operated in a rational way for the more than 800 CERCLA hazardous substances already within its purview, some of which are similar to PFOA and PFOS in terms of ubiquity, mobility, and persistence. Heavy metals, such as arsenic and chromium, are persistent, and in at least some places, prevalent in the environment. Although EPA understands that designation will result in new litigation regarding PFOA and PFOS releases for responsible parties, forty years of CERCLA experience indicates that designation should not result in unusual CERCLA liability or litigation outcomes for parties who did not significantly contribute to the contamination as a result of this designation, and, therefore, the potential for litigation should not be a barrier to designation.

EPA aims to further support reasonable liability and litigation outcomes through the implementation of its CERCLA enforcement program. EPA will continue to implement its ''Enforcement First'' policy (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,'' 1982*)—in which EPA aims to compel viable PRPs to conduct and pay for investigation and cleanup before resorting to the Fund—which supports the Polluter Pays principle. EPA has a proven track record of developing and applying enforcement discretion policies that are effective and well-received by the public and interested parties, and courts have sanctioned this approach. Enforcement discretion policies historically have given EPA the needed flexibility to offer liability comfort or protections when circumstances warrant. For example, for more than 30 years, EPA has maintained its ''Policy Towards Owners of Residential Property at Superfund Sites,'' which generally provides that EPA will not take action against residential property owners provided their own actions do not cause a release that requires a response action.

Although EPA believes existing limitations in CERCLA coupled with existing CERCLA enforcement policies mitigate concerns about liability that may arise after designation, EPA recognizes that some parties that do not bear primary responsibility for litigation may be sued and face uncertain litigation costs as a consequence. EPA believes that the statutory safeguards described above will likely limit this type of litigation, or at a minimum, limit adverse outcomes. Even if litigation costs are incurred by parties that do not bear primary responsibility, EPA does not believe that these potential costs will outweigh the substantial advantages from the rule.

While some commenters shared concerns that these mechanisms may not mitigate concerns, these commenters did not support their concerns with any specific data or evidence. Generally, in enforcement matters, the facts, circumstances, and equities of a case help dictate which parties the Agency will pursue. EPA, intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for enforcement in the context of PFOA and PFOS releases.[19] As EPA states in the FY 2024–2027 National Enforcement and Compliance Initiatives (NECI), the Agency expects to ''focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment . . . much as [EPA] exercises CERCLA enforcement discretion in other areas.''.[20] Available at *https://www.epa.gov/system/files/documents/2023-08/fy2024-27necis.pdf*.

In sum, EPA's additional ''totality of the circumstances'' analysis affirms that designation is warranted. The totality of the circumstances analysis gave particular weight to the scientific basis for designation—that PFOA and PFOS may present substantial danger when released into the environment. EPA also concluded that designation best addresses the problem posed by PFOA and PFOS in the environment, particularly for those communities living in and around highly contaminated sites, and that designation meaningfully furthers CERCLA's purposes. Designation ensures that EPA has the full suite of CERCLA tools necessary to address contamination and that EPA is able to take more timely response actions, including those necessary to address immediate risks. EPA's analysis shows that designation results in quantitative and qualitative benefits, including significant health

[17] CERCLA is designed to achieve the cleanup of contaminated sites by ensuring that those responsible for the contamination pay to clean it up, which EPA supports through its longstanding ''enforcement first'' policy. (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,*'' 1982.) Furthermore, CERCLA's settlement provisions are designed to support and achieve those outcomes by making it efficient for EPA to secure clean up from those that have significantly contributed to contamination. *See, e.g.* Section 122(a) (''Whenever practical and in the public interest, . . . [EPA] shall act to facilitate agreements . . . that are in the public interest and minimize litigation.''); Section 122(g)(1) (allowing for ''expedited'' *de minimis* settlements for ''minor portions of the response costs''). In practice, CERCLA's settlement parameters incentivize PRPs that likely bare a large share of responsibility to settle with EPA, which in turn can deter those same parties from pursuing other PRPs. Ultimately, settlement is generally less expensive than litigation and can serve as an effective mechanism for achieving the true goal of CERCLA—that the parties most responsible for contamination pay to clean it up.

[18] While EPA's enforcement discretion policies themselves are not regulations and do not create new legal obligations or limit or expand obligations under any federal, state, tribal or local law, such policies have influenced Congress to create new laws that have been upheld by courts. The Small Business Liability Relief and Brownfields Revitalization Act of 2002 (''Brownfields Amendments'') illustrate how EPA's policies have influenced Congressional action. The Brownfields Amendments amended CERCLA and promoted the cleanup, reuse, and redevelopment of sites by addressing potential liability concerns associated with contaminated, potentially contaminated, and formerly contaminated properties. The Brownfields Amendments provided important self-implementing liability limitations for certain categories of landowners, enabling private parties to save time and costs, in part, by reducing EPA involvement in most private party transactions. EPA launched the Brownfields Initiative in the 1990s and developed guidance and tools to help further the Initiative's goals to empower states, communities, and other stakeholders to assess, safely clean up, sustainably reuse, and prevent future brownfield sites. EPA's Brownfields Initiative established a number of practices, policies, and guidances to support cleanup and reuse at contaminated property. In 2002, many elements of EPA's Brownfields Initiative were codified into CERCLA by the Brownfields Amendments.

[19] EPA received valuable public input that EPA is considering in drafting a CERCLA PFAS enforcement discretion policy. EPA held two public listening sessions in March 2023 and several stakeholder meetings in 2023 with the agriculture sector, water sector, pulp and paper sector, solid waste management sector, and NGOs to hear stakeholder concerns regarding potential CERCLA PFAS enforcement concerns.

[20] *https://www.epa.gov/enforcement/national-enforcement-and-compliance-initiatives.*

benefits. EPA's analysis accounts for potential direct and indirect costs that may result from designation. Direct costs, particularly for release notifications, are minimal and reasonable in light of the substantial benefits notification provides. EPA assessed the potential for litigation and liability costs, particularly for parties that have not significantly contributed to contamination. EPA was unable to quantify those costs with reasonable certainty but conducted a qualitative assessment of CERCLA's liability provisions and enforcement policies to assess the potential magnitude of such costs. EPA's analysis shows that designation should not result in excessive or unreasonable liability and litigation outcomes. Rather, CERCLA will continue to operate as it has for decades. EPA concludes that the substantial advantages of designation outweigh potential disadvantages, and that designation is warranted based on its additional totality of the circumstances analysis.

D. Conclusion

EPA concludes that designation is warranted based solely on its finding that PFOA and PFOS may present a substantial danger to the public health or welfare or the environment when released into the environment. Additionally, EPA believes designation is warranted based on its totality of the circumstances analysis. The latest science is clear: human exposure to PFOA and PFOS is linked to significant health risks. CERCLA provides the tools necessary to address those risks posed by significant contamination of PFOA and PFOS in the environment. CERCLA is designed to target and prioritize sites that present unreasonable risk to human health and the environment and serves those communities that are most vulnerable to potential adverse health risks from exposure. Designation eliminates barriers to cleanup and enables EPA to secure more timely actions. It streamlines response authority, provides a mechanism for parties to recover response costs from PRPs, and makes available CERCLA enforcement authority to compel PRPs to conduct or pay for cleanup. Designation also requires facilities to notify Federal, State, local, and Tribal authorities, as well as potentially injured parties, of significant releases. EPA considered the potential costs that may arise after designation, including both quantified and unquantified costs, and finds that they are outweighed by the substantial advantages of designation. Further delay in accessing CERCLA's complete suite of tools to address contamination will allow PFOA and PFOS more time to migrate within the environment and exacerbate existing contamination. Thus, designation best achieves CERCLA's primary objectives—the timely cleanup of contaminated sites and ensuring that those responsible for contamination pay to clean it up. Designation will help protect communities near contaminated sites from potential health risks. For all these reasons, discussed in detail below, EPA concludes that designation of both PFOA and PFOS as CERCLA hazardous substances is warranted under the statute.

II. General Information

A. What action is the Agency taking?

As proposed on September 6, 2022, EPA is designating PFOA and PFOS, including their salts and structural isomers, as hazardous substances under section 102(a) of CERCLA. *See Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* 87 FR 54415 (Sept. 6, 2022). The list of hazardous substances in Table 302.4 of 40 CFR part 302 is amended to include PFOA, PFOS and their salts and structural isomers. (*Note: EPA's CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard/) is a resource that can be used to identify salts and structural isomers of PFOA and PFOS. EPA periodically updates the CompTox Chemicals Dashboard to include new information on PFAS, including PFOA and PFOS.)*

B. What are the direct effects of this Action?

The designation of PFOA and PFOS, including their salts and structural isomers, as hazardous substances, can trigger the applicability of release reporting requirements under CERCLA sections 103 and 111(g), and accompanying regulations, and section 304 of the Emergency Planning and Community Right-to-Know Act (EPCRA). Facilities must report releases of hazardous substances at or above the reportable quantity (RQ) within a 24-hour period. For PFOA and PFOS, a default [21] reportable quantity (RQ) of one pound is assigned to these substances pursuant to CERCLA section 102(b). Therefore, consistent with CERCLA section 103(a), any person in charge of a vessel or facility is required, as soon as they have knowledge of any release (other than a federally permitted release) of any PFOA, PFOS, their salts or structural isomers from such vessel or facility in quantities equal to or greater than the RQ of one pound or more within a 24-hour period, to immediately notify the National Response Center (NRC) of such a release. The reporting requirements are further codified in 40 CFR 302.6(a). *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6.*

In addition to CERCLA 103(a), EPCRA section 304 requires facility owners or operators to immediately notify their community emergency coordinator for local emergency planning committee (LEPC) (or Tribal emergency planning committee (TEPC)), if established, for any area likely to be affected by the release and to notify the State Emergency Response Commission (SERC) (or Tribal Emergency Response Commission (TERC)) of any State or Tribal region likely to be affected by the release of these substances. These entities may have specific release reporting requirements under the State, Tribal, and local EPCRA program. *https://www.epa.gov/epcra/state-contact-information-epcra-section-304-emergency-release-notification.*

EPCRA section 304 also requires facilities to submit a follow-up written report to their SERC (or TERC) and the LEPC (or TEPC) as soon as practicable after the release. EPCRA section 304 requirements are codified in 40 CFR 355.30 to 355.43. *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-355/subpart-C.*

CERCLA section 111(g) requires that owners or operators of any vessel or facility ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area'' of any release of these substances.

CERCLA section 120(h) requires Federal agencies that sell or transfer real property to provide notice of the presence of hazardous substances in certain circumstances. CERCLA section 120(h) also requires Federal agencies to provide a covenant warranting that ''all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States.''

As provided by CERCLA section 306, the Department of Transportation (DOT) is required to regulate any substance added to the CERCLA list as hazardous materials in accordance with the Hazardous Materials Transportation Act (HMTA).

[21] 42 U.S.C. 9602(b). *https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap103-subchapI-sec9601.pdf.*

While these are the only direct, automatic requirements of designating PFOA and PFOS as CERCLA hazardous substances, EPA has also considered other, indirect impacts in the *Regulatory Impact Analysis (RIA) of the Final Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* available in the docket, including those that are expected to facilitate cleanups and reduce human and environmental exposure to these hazardous substances.

C. Does this Action apply to me?

The seven broad categories of entities that may potentially be affected by this action include, but are not limited to: (1) PFOA and/or PFOS manufacturers (including importers and importers of articles that contain these substances); (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream users of PFOA and PFOS; (5) downstream users of PFOA and/or PFOS products; (6) waste management facilities; and (7) wastewater treatment facilities.[22] (*Note: PFOA and PFOS noted here include their salts and structural isomers.*) The following list of North American Industrial Classification System (NAICS) codes identifies entities that may be directly or indirectly affected by this action. It is not intended to be exhaustive, but rather a guide to help readers determine whether this action applies to them. Potentially affected entities may include:

BILLING CODE 6560–50–P

[22] The proposed rule listed 5 broad categories of entities potentially affected by this designation. This action separated two of these categories to be clearer. Entities listed as downstream product manufacturers and users of PFOA and/or PFOS products in the proposed rule are split into two separate categories in the final rule (see (4) and (5)). Entities listed as waste management and wastewater treatment facilities in the proposed rule are split into two categories in the final rule (see (6) and (7)).

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Oil and Gas Extraction	Oil and Gas Extraction	211120	Crude Petroleum Extraction
		211130	Natural Gas Extraction
Mining (except Oil and Gas)	Metal Ore Mining	212221	Gold Ore Mining
		212230	Copper, Nickel, Lead, and Zinc Mining
		212291	Uranium-Radium-Vanadium Ore Mining
Utilities	Water, Sewage and Other Systems	221320	Sewage Treatment Facilities
Textile Mills	Fiber, Yarn, and Thread Mills	313110	Fiber, Yarn, and Thread Mills
	Fabric Mills	313210	Broad Woven Fabric Mills
		313220	Narrow Fabric Mills and Schiffli Machine Embroidery
		313230	Nonwoven Fabric Mills
		313240	Knit Fabric Mills
	Textile and Fabric Finishing and Fabric Coating Mills	313310	Textile and Fabric Finishing Mills
		313320	Fabric Coating Mills
Textile Product Mills	Textile Furnishings Mills	314110	Carpet and Rug Mills
	Other Textile Product Mills	314910	Textile Bag and Canvas Mills
		314999	All Other Miscellaneous Textile Product Mills
Leather and Allied Product Manufacturing	Leather and Hide Tanning and Finishing	316110	Leather and Hide Tanning and Finishing
	Other Leather and Allied Product Manufacturing	316998	All Other Leather Good and Allied Product Manufacturing
Paper Manufacturing	Pulp, Paper, and Paperboard Mills	322121	Paper (except Newsprint) Mills
		322130	Paperboard Mills
	Converted Paper Product Manufacturing	322219	Other Paperboard Container Manufacturing
		322220	Paper Bag and Coated and Treated Paper Manufacturing
Printing and Related Support Activities	Printing and Related Support Activities	323111	Commercial Printing (except Screen and Books)
		323120	Support Activities for Printing
Petroleum and Coal Products Manufacturing	Petroleum and Coal Products Manufacturing	324110	Petroleum Refineries
		324191	Petroleum Lubricating Oil and Grease Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Chemical Manufacturing	Basic Chemical Manufacturing	325110	Petrochemical Manufacturing
		325120	Industrial Gas Manufacturing
		325130	Synthetic Dye and Pigment Manufacturing
		325180	Other Basic Inorganic Chemical Manufacturing
		325193	Ethyl Alcohol Manufacturing
		325199	All Other Basic Organic Chemical Manufacturing
	Resin, Synthetic Rubber, and Artificial and Synthetic Fibers and Filaments Manufacturing	325211	Plastics Material and Resin Manufacturing
		325212	Synthetic Rubber Manufacturing
		325220	Artificial and Synthetic Fibers and Filaments Manufacturing
	Pesticide, Fertilizer, and Other Agricultural Chemical Manufacturing	325320	Pesticide and Other Agricultural Chemical Manufacturing
	Pharmaceutical and Medicine Manufacturing	325411	Medicinal and Botanical Manufacturing
	Paint, Coating, and Adhesive Manufacturing	325510	Paint and Coating Manufacturing
	Soap, Cleaning Compound, and Toilet Preparation Manufacturing	325611	Soap and Other Detergent Manufacturing
		325612	Polish and Other Sanitation Good Manufacturing
		325613	Surface Active Agent Manufacturing
	Other Chemical Product and Preparation Manufacturing	325910	Printing Ink Manufacturing
		325992	Photographic Film, Paper, Plate, and Chemical Manufacturing
		325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
Plastics and Rubber Products Manufacturing	Plastics Product Manufacturing	326112	Plastics Packaging Film and Sheet (including Laminated) Manufacturing
		326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing
		326121	Unlaminated Plastics Profile Shape Manufacturing
		326130	Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
	Rubber Product Manufacturing	326211	Tire Manufacturing (except Retreading)
Nonmetallic Mineral Product Manufacturing	Glass and Glass Product Manufacturing	327215	Glass Product Manufacturing Made of Purchased Glass
	Cement and Concrete Product Manufacturing	327310	Cement Manufacturing
	Other Nonmetallic Mineral Product Manufacturing	327999	All Other Miscellaneous Nonmetallic Mineral Product Manufacturing
Primary Metal Manufacturing	Steel Product Manufacturing from Purchased Steel	331221	Rolled Steel Shape Manufacturing
	Alumina and Aluminum Production and Processing	331313	Alumina Refining and Primary Aluminum Production
Fabricated Metal Product Manufacturing	Coating, Engraving, Heat Treating, and Allied Activities	332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers
		332813	Electroplating, Plating, Polishing, Anodizing, and Coloring
	Other Fabricated Metal Product Manufacturing	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing
Machinery Manufacturing	Industrial Machinery Manufacturing	333249	Other Industrial Machinery Manufacturing
	Commercial and Service Industry Machinery Manufacturing	333316	Photographic and Photocopying Equipment Manufacturing
		333318	Other Commercial and Service Industry Machinery Manufacturing
Computer and Electronic Product Manufacturing	Communications Equipment Manufacturing	334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing
	Audio and Video Equipment Manufacturing	334310	Audio and Video Equipment Manufacturing
	Semiconductor and Other Electronic Component Manufacturing	334412	Bare Printed Circuit Board Manufacturing
		334413	Semiconductor and Related Device Manufacturing
		334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing
		334419	Other Electronic Component Manufacturing
Electrical Equipment,	Other Electrical Equipment and	335931	Current-Carrying Wiring Device Manufacturing

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Appliance, and Component Manufacturing	Component Manufacturing	335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing
Transportation Equipment Manufacturing	Motor Vehicle Parts Manufacturing	336399	All Other Motor Vehicle Parts Manufacturing
Miscellaneous Manufacturing	Medical Equipment and Supplies Manufacturing	339112	Surgical and Medical Instrument Manufacturing
Merchant Wholesalers, Nondurable Goods	Chemical and Allied Products Merchant Wholesalers	424690	Other Chemical and Allied Products Merchant Wholesalers
	Petroleum and Petroleum Products Merchant Wholesalers	424710	Petroleum Bulk Stations and Terminals
Furniture and Home Furnishings Stores	Home Furnishings Stores	442291	Window Treatment Stores
Rail Transportation	Rail Transportation	482111	Freight Rail
Truck Transportation	General Freight Trucking	484110	Truck Freight
Support Activities for Transportation	Support Activities for Air Transportation	488119	Other Airport Operations
	Support Activities for Water Transportation	488310	Port and Harbor Operators
Administrative and Support Services	Services to Buildings and Dwellings	561740	Carpet and Upholstery Cleaning Services
Waste Management and Remediation Services	Waste Collection	562112	Hazardous Waste Collection
	Waste Treatment and Disposal	562211	Hazardous Waste Treatment and Disposal
		562212	Solid Waste Landfill
		562213	Solid Waste Combustors and Incinerators
		562219	Other Nonhazardous Waste Treatment and Disposal
Repair and Maintenance	Automotive Repair and Maintenance	811192	Car Washes
	Personal and Household Goods Repair and Maintenance	811420	Reupholstery and Furniture Repair
Personal and Laundry Services	Drycleaning and Laundry Services	812300	Dry Cleaner and Laundry Operators

Sector	Industry Group	6-Digit NAICS	6-Digit NAICS Description
Justice, Public Order, and Safety Activities	Justice, Public Order, and Safety Activities	922160	Fire Protection
National Security and International Affairs	National Security and International Affairs	928110	National Security

BILLING CODE 6560–50–C

D. What is the Agency's authority for taking this action?

CERCLA section 102(a) authorizes the EPA Administrator to ''promulgate and revise as may be appropriate, regulations designating as hazardous substances, . . . such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment[.]'' CERCLA section 102(b) establishes a default RQ of one pound for releases of designated hazardous substances. *See Section IV of this document for additional details on EPA's authority, including statutory criteria.*

E. What are CERCLA's primary objectives, and how does it operate to protect human health and the environment?

CERCLA establishes broad Federal authority to address past, current, and future releases or threat of releases of hazardous substances and pollutants or contaminants. The statute's primary objectives are to promote the timely cleanup of contaminated sites and to ensure parties responsible for contamination bear site cleanup costs. CERCLA is unlike traditional environmental statutes that prospectively regulate, among other things, how facilities operate and provide limitations on discharges, emissions, releases, or disposal of certain chemicals into water, air, or land. Instead, CERCLA is designed to address contamination already in the environment on a site-specific basis, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. CERCLA affords EPA broad discretion as to whether or how to respond to a release. It includes cost-shifting mechanisms and liability provisions that support PRP cleanups rather than relying on the Fund.

1. How does CERCLA authority and causes of action differ in key respects between ''hazardous substances'' and ''pollutants or contaminants''?

For hazardous substances,[23] CERCLA section 103(a) requires reporting of releases. CERCLA requires any person in charge of a vessel or facility to immediately notify the NRC when there is a release of a hazardous substance in an amount equal to or greater than the RQ for that substance. Notice given to the NRC under CERCLA serves to inform the Federal Government of a release so that Federal personnel can evaluate the need for a response pursuant to CERCLA and its accompanying regulations, the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). (40 CFR part 300).

CERCLA response authorities apply to releases or the threat of releases into the environment of ''hazardous substances'' and/or ''pollutants or contaminants'' [24]; however, the CERCLA authorities available to address each type of release differs. With respect to *hazardous substances,* the Agency can conduct response actions if there is a release or threatened release; however, for pollutants or contaminants, EPA can only respond if it establishes that the release may present an imminent and substantial danger. (CERCLA section 104(a)).

In addition, CERCLA's cost recovery and some specific enforcement authorities extend to hazardous substances but not pollutants or contaminants. (CERCLA section 107(a), 106(a)). For hazardous substances, EPA can recover all response costs (*e.g.,* investigation and cleanup costs) from PRPs the Agency incurs that are not inconsistent with the NCP and require PRPs to conduct the response. CERCLA also authorizes non-governmental entities (including private parties) who conduct cleanup activities related to hazardous substance releases to recover response costs from liable parties provided the costs incurred are consistent with the NCP.

2. What response actions does CERCLA authorize?

CERCLA authorizes two types of response actions—removal and remedial. (CERCLA section 101(25)). Removals include ''such actions as may be necessary taken in the event of the threat of release,'' including those ''necessary to prevent, minimize, or mitigate damage to the public health or welfare or the environment.'' (CERCLA section 101(23)). Removals are typically short-term response actions that may be taken to address releases or threatened releases requiring prompt action; they are limited in cost and duration unless specific criteria are met. (CERCLA section 104(c)(1)). Remedial includes those actions consistent with ''permanent remedy taken instead of or in addition to removal actions in the event of a release or threatened release of a hazardous substance into the environment, to prevent or minimize the release of hazardous substances so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment'' (CERCLA section 101(24)). Remedial actions (RAs) entail longer-term and more complex cleanup actions designed to provide permanent solutions to mitigate risks typically associated with chronic exposures often not immediately life-threatening.

[23] CERCLA defines ''hazardous substance'' primarily by reference to other environmental statutes (*i.e.,* the Clean Water Act, Solid Waste Disposal Act, Clean Air Act and the Toxic Substances Control Act) and includes substances designated as hazardous under CERCLA section 102. (CERCLA section 101(14)).

[24] CERCLA defines the term ''pollutant or contaminant'' to include, ''but not be limited to, any element, substance, compound, or mixture . . . which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism . . . will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions . . . or physical deformations.'' (CERCLA 104).

3. What discretionary authority does CERCLA provide and how does CERCLA prioritize cleanup actions?

EPA has broad discretionary authority to decide on a site-specific basis whether to respond to a release or threat of release and to prioritize the order in which it undertakes response actions determined to be necessary. (CERCLA section 105(a)(8)(A)). Site-specific decisions take into consideration factors such as relative risk, hazard potential, population at risk and the potential for drinking water contamination. Those considerations are embodied in the NCP. (*See, e.g.,* 40 CFR 300.410, 300.415, 300.430).

4. What is the CERCLA cleanup process and what role does the National Priorities List (NPL) play in it?

Before identifying an appropriate response action—removal or remedial—EPA or another lead agency, may first identify a release, investigate its scope and extent, and evaluate its potential risk to human health and the environment. Superfund cleanups typically begin with a preliminary assessment/site inspection, which includes reviews of historical information and site visits to evaluate the potential for a release of hazardous substances (CERCLA section 104(b); 40 CFR 300.410, 300.430(b)). After an initial investigation, EPA has several options, including determining a release does not pose sufficient risk to warrant further action and deciding that the release warrants a CERCLA response action. EPA may also defer the site to the State where it is located.

The NCP provides guidance on the process to determine whether to undertake a removal or a remedial action. For removal actions, the NCP provides that the lead agency may take such an action when it has determined ''that there is a threat to public health or welfare'' based on a set of factors such as actual or potential exposure to drinking water supplies, the potential for hazardous substances to migrate, and the availability of other appropriate Federal or State response mechanisms to address the release. (40 CFR 300.415(b)). For remedial actions, EPA first evaluates a site for consideration as an NPL site, (40 CFR part 300 App. A); only sites added to the NPL are eligible for Superfund monies to conduct remedial actions.

A site's addition to the NPL does not trigger any immediate action but represents an initial step towards a site's potential long-term remedy; NPL sites are among the Nation's worst contaminated sites. EPA has placed on the NPL only about 3 percent of the 53,400 sites assessed since the program's beginning in 1980.

5. What is the process for identifying and selecting remedial actions under CERCLA?

EPA can only begin the process to identify potential remedial actions after completing the careful and deliberate process to add a site to the NPL. CERCLA and the NCP together prescribe a comprehensive and detailed process for evaluating, selecting, and implementing remedies, which includes State and community roles. (40 CFR 300.430). The process' first step is conducting a remedial investigation and feasibility study (RI/FS) to assess site conditions and to evaluate the remedial alternatives identified. (40 CFR 300.430(a)(2)). Next, the NCP mandates consideration of several factors by which to evaluate remedial alternatives. (40 CFR 300.430(e)(9)). At a minimum, all eligible remedies must be protective of human health and the environment and comply with all applicable or relevant and appropriate requirements (ARARs).[25] (CERCLA section 121(a), (d); 40 CFR 300.430(f)(1)(i)(A)). The alternatives satisfying these two threshold criteria are then further evaluated against one another using balancing criteria, including factors such as long-term effectiveness and permanence; toxicity, mobility or volume reduction; implementability; cost; and finally modifying criteria of State acceptance; and community acceptance. (40 CFR 300.430(e)(9), (f)).

A remedial action's selection must include public review and comment on the lead agency's preferred alternative as presented in a proposed plan. (CERCLA section 117; 40 CFR 300.430(f)(2)). EPA documents its selection of a remedy in a record of decision. (40 CFR 300.430(f)(1)(ii)).

A site's selected remedy then enters the remedial design (RD)/remedial action (RA) stage in which the remedy is designed and constructed, followed in some instances by an Operation & Maintenance (O&M) period.[26] (40 CFR 300.435(a), (f)). Five-year reviews (FYR)[27] are required at sites where completed remedial actions result in any hazardous substances, pollutants, or contaminants remaining onsite. (CERCLA section 121(c)). They also must be conducted where remedial actions result in any hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure after the initiation of the selected remedial action. (40 CFR 300.430(f)(4)(ii)).

6. How does CERCLA's framework ensure that those responsible for contamination pay for cleanup?

A critical CERCLA component is holding those responsible for the contamination accountable to perform or pay for its cleanup. EPA's preference, and one of CERCLA's main goals, is to have PRPs be responsible for the cleanup of releases of hazardous substances. EPA can compel a PRP to take action pursuant to a CERCLA enforcement instrument. (CERCLA section 106). EPA can also perform the response action using Fund money and then seek reimbursement of costs incurred from liable parties in litigation, (CERCLA section 107(a)), or subsequent cost recovery settlement (CERCLA section 122(a)). Under CERCLA, potentially liable parties include: (1) current owners and operators of facilities, (2) past owners and facility operators in place at the time of hazardous substance disposal, (3) any person who ''arranged for disposal'' of that facility's hazardous substances, and (4) any person that accepts hazardous substances for ''transport to disposal or treatment facilities.'' (CERCLA section 107(a)(1)–(4)). If found liable under the statute, a PRP is financially responsible for the government's response costs incurred not inconsistent with the NCP in addition to other categories of costs. (CERCLA section 107(4)(A)–(D).

[25] ARARs may be waived under certain circumstances. (CERCLA section 121(d)(4)).

[26] O&M is an important component of a Superfund response, ensuring that the remedy continues to perform as intended and remains protective of human health and the environment. O&M activities may include remedy operation, maintenance and monitoring, as well as monitoring of impacted media and monitoring and maintenance of implemented Institutional Controls (ICs)s. ICs are non-engineered instruments, such as administrative and/or legal controls, that help minimize the potential for human exposure to contamination and/or protect the integrity of a remedy by limiting land or resource use. Examples include fishing restrictions, deed restrictions, and the posting of warning signs outside of a contaminated site.

[27] Five-year reviews evaluate the implementation and performance of a remedy to determine whether it remains protective.

7. What enforcement discretion is available when exercising CERCLA authority?

EPA has a proven track record of developing and applying enforcement discretion policies that are effective and well-received, and courts have sanctioned this approach. CERCLA's limitations and EPA's enforcement discretion policies historically have given EPA the needed flexibility to provide assurances when circumstances warrant. Although CERCLA's liability scheme is broad, the statutory affirmative defenses and EPA's enforcement discretion policies provide mechanisms to narrow the scope of liability and focus on the significant contributors to contamination.

Both the statute and EPA enforcement discretion policies may constrain a party's ability to secure reimbursement of response costs. CERCLA itself includes liability exemptions as well as affirmative defenses against liability. *See, e.g.,* CERCLA section 101(10), 107(b), (d), (k). Additionally, parties must prove that response costs incurred are consistent with the National Contingency Plan, CERCLA's implementing regulations. *Id.* section 107(a)(4)(B). Parties must also incur response costs before they can recover those costs from other viable, liable parties. EPA's enforcement authorities and policies can serve as a deterrent for responsible parties to pursue parties that did not contribute significantly to contamination. EPA has a well-proven track record of developing enforcement discretion policies that have been effective and well-received by stakeholders. EPA's enforcement policies, such as its policy regarding de minimis or de micromis parties and innocent landowner policies, have proven to be useful tools in convincing responsible parties not to pursue parties covered by these enforcement discretion policies. Finally, the statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled to contribution protection—the ability to block third-party claims for matters addressed in the settlement. These liability limitations and mitigation tools are more fully discussion in Section VI.B.2.

8. Why is understanding CERCLA's overarching provisions critical to understanding the importance of this rulemaking to EPA's ability to protect human health and the environment?

Understanding CERCLA's basic concepts, particularly its liability scheme and CERCLA's authority to address hazardous substances (versus its authorities to respond to pollutants or contaminants) are essential to understanding this regulatory action's importance in protecting human health and the environment. Designating PFOA and PFOS as hazardous substances is an important step for EPA to take because it makes available the full suite of CERCLA tools to address releases of these substances. Designation provides a more streamlined path to respond to PFOA and PFOS releases. It also makes available CERCLA enforcement authority that EPA can use to compel PRPs to pay for or conduct CERCLA response actions, rather than EPA using the Fund to clean up. Designation is expected to expedite PFOA and PFOS cleanups, and in turn, mitigate risks to public health and the environment from these substances.

III. Background for This Rulemaking

A. Summary of Proposed Designation

On September 6, 2022 (87 FR 54415), EPA proposed to find that PFOA and PFOS and their salts and structural isomers warrant designation as hazardous substances pursuant to CERCLA section 102(a). EPA concluded that significant evidence indicates that PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released. (87 FR 54417, 54423). In reaching the proposed conclusion, the Agency relied on a significant body of evidence showing that PFOA and PFOS are persistent and mobile in the environment and that exposure to such substances may lead to adverse health effects.

The Agency primarily relied on evidence concerning the hazard and fate and transport, as well as other information that may be relevant to whether the statutory criteria are met. EPA looked at scientific and technical data regarding toxicity and toxicokinetics, chemical and physical characteristics, and environmental prevalence of PFOA and PFOS to support the proposed finding that these chemicals may present substantial danger when released into the environment. *See* Proposed Rule, 87 FR at 54423–29. In short, the evidence related to the chemical and physical characteristics indicated that PFOA and PFOS are persistent in the environment and that they bioaccumulate in both humans and wildlife. The evidence also showed that PFOA and PFOS are distinct from many other bioaccumulative chemicals because their water solubility allows PFOA and PFOS to more readily migrate from soil to groundwater; thus, their release into the environment has the potential to contaminate both surface water and groundwater used as drinking water sources.

Concerning the toxicity and toxicokinetics, both human and animal studies supported a conclusion that exposure to PFOA and PFOS may cause adverse health effects, including effects on the immune system, the cardiovascular system, fetus development, and cancer. The evidence also showed that PFOA and PFOS are prevalent in the environment because they have been produced and used since the 1940s and are resistant to degradation. The evidence showed that PFOA and PFOS are not only prevalent in humans, but also prevalent in environmental media, wild animals, livestock, and plants. EPA concluded that the prevalence of these substances impacts the environment directly and increases the likelihood of exposures that may lead to additional human exposure.

The adverse human health effects, mobility, persistence, prevalence, and other information about PFOA and PFOS combined to support EPA's proposed finding that these chemicals may present a substantial danger to public health or welfare or the environment when released such that designation of PFOA and PFOS as CERCLA hazardous substances is warranted.

B. PFOA and PFOS Production and Use

PFOA and PFOS are part of a large family of human-made chemicals known as PFAS that have been in use in the U.S. since the 1940s. PFAS, including PFOA and PFOS, are used in industry and consumer products because of their useful properties, including their resistance to water, grease, and stains. These substances have been found in or used in making a wide range of consumer products including carpets, clothing, fabrics for furniture, and packaging for food and cookware that are resistant to water, grease, or stains. They have also been used for firefighting and various industrial processes. In terms of their chemistry, they exist as linear and branched isomers, depending on the methods by which they are produced. Both PFOA and PFOS have been manufactured in numerous salt forms. Once dissolved in water, the salt and the acid forms will dissociate into the respective ions. *See* Proposed Rule, 87 FR at 54417 (providing a brief history of PFOA and PFOS production and use).

Production and use of these chemicals have resulted in releases into the

environment for many decades. Historic releases of PFOA and PFOS are significant sources of environmental contamination and present ongoing hazards to human health and the environment. Precursors of PFOA and PFOS can be converted to PFOA and PFOS by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. PFOA and PFOS that are deposited or created by the degradation of their precursors in industrial and consumer waste or in a landfill without environmental controls can discharge via leachates, groundwater pollution/migration, and atmospheric releases.

PFAS have been detected in the ambient environment, in wildlife, and in humans around the globe, and PFOA and PFOS were among the most used PFAS from the beginning of their development in the 1940s (*Blake & Fenton, 2020; Calafat et al., 2007; Domingo & Nadal, 2019; Hanssen et al., 2013; Olsen et al., 2017*). The potential health risks associated with PFAS were first recognized in occupationally exposed workers in the 1980s and community level exposure concerns were first raised in 1998. Since that time, the U.S. government, including EPA, and many other environmental and human health organizations both within the U.S. and internationally have researched PFAS to determine the risks posed by exposure to such chemicals. The additional evaluation since the late 1990s has added support for early concerns that exposure to PFAS may present a risk and that exposure to long chain PFAS, such as PFOA and PFOS, are of particular concern because of, among other things, their prevalence in the environment, mobility, and resistance to degradation.

In response to the growing body of evidence concerning the potential risks, Federal, State, and international agencies have taken steps to mitigate exposure to PFOA and PFOS. For example, in 2016, the FDA revoked a regulation that allowed the use of long chain PFAS in food contact applications in the U.S.; the DoD added PFOA and PFOS to its list of emerging chemicals of concern and is in the process of requiring any of its new firefighting foam it purchases to be made without PFAS per a January 2023 military specification; several States have established groundwater cleanup standards for PFOA and/or PFOS; and PFAS, including PFOA and PFOS, are addressed in several international treaties.[28]

Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program (*U.S. EPA, 2023c, 2023d*). Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (*U.S. EPA, 2023a*). The EPA Chemical Data Reporting (CDR) rule (*see* 40 CFR 721.9582) under TSCA requires manufacturers (including importers) to report certain data about chemicals in commerce in the United States, including information on PFOA and PFOS (subject to a 2,500-pound reporting threshold at a single site). The last time PFOA and PFOS manufacturing information was reported to EPA pursuant to CDR was in 2013 and 2002, respectively. The reports showed that these chemicals were still being produced or used in those reporting years, however manufacturers did not report PFOA and PFOS in excess of the reporting limit in subsequent reporting cycles. However, 2020–2022 Toxic Release Inventory (TRI) data show that PFOA and PFOS continue to be released into the environment, which means that there are on-going uses of these substances. Pursuant to TRI reporting requirements, regulated facilities must report annually on releases and other waste management of toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities. The TRI reporting threshold for PFOA and PFOS is 100 pounds. Between 2020 and 2022, TRI data on releases[29] of PFOA, PFOS, and their salts[30] reported by 21 facilities amount to 71,411 lbs. In 2020, TRI data on releases of PFOA, PFOS, and their salts reported by nine facilities totaled 1,706 lbs. In 2021 and 2022, reported releases increased to 24,351 lbs. and 45,384 lbs., respectively.[31] PFOA is not produced domestically or imported by the companies participating in the 2010/2015 PFOA Stewardship Program. However, based on the TRI report, it is possible that PFOA may still be produced domestically or imported by companies that did not participate in the PFOA Stewardship Program and that PFOS may be as well.

Environmental contamination and resulting human exposure to PFOA and PFOS are anticipated to continue for the foreseeable future due to their past wide-scale manufacture and use, environmental persistence, formation from precursor compounds, and continued limited domestic production and use. Although PFOA and PFOS levels have been decreasing in human serum samples since the phase out, they are still detected in a high percentage of the U.S. population (NHANES). This indicates humans are still being exposed to PFOA and PFOS.

C. EPA's PFAS Strategic Roadmap

EPA issued the PFAS Strategic Roadmap (Roadmap) in October 2021, wherein the Agency recognized the potential dangers posed by exposure to PFAS and committed to a comprehensive whole-of-Agency plan to address PFAS (*U.S. EPA, 2021a*). EPA's integrated approach to PFAS is focused on three central directives: (1) *Research.* Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science; (2) *Restrict.* Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment; and (3) *Remediate.* Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems. The Roadmap committed to an Agency-wide approach, in which EPA would utilize the tools at its disposal to urgently address PFAS and bring tangible health benefits to communities impacted by PFAS. EPA identified a variety of authorities to address PFAS, including the TSCA, the Safe Drinking Water Act (SDWA), CWA, and RCRA, in addition to CERCLA. The Agency recognized that each authority has a unique set of tools to address discrete and specific environmental challenges posed by PFAS. Since 2021, EPA has taken several actions to address PFAS contamination under the Agency's various regulatory programs. *Visit Agency's website at https://www.epa.gov/pfas/key-epa-actions-address-pfas.*

---

[28] See Proposed Rule, 87 FR at 54429–39 (providing a list of regulatory and other PFAS related actions at EPA, other Federal Agencies, states, and international agencies).

[29] Facilities are required to report total releases per year of listed toxic chemicals into the environment (*e.g.,* releases to land on-site, discharges to receiving streams or water bodies, etc.). *https://www.ecfr.gov/current/title-40/part-372/subpart-E#p-372.85(b)(14)* (40 CFR 372.85(b)(14).

[30] As of November 2023, the list of toxic chemicals under the TRI program include 8 salts, as well as PFOA and PFOS, that are also listed as CERCLA HSs in this final action.

[31] In addition to these releases, the TRI also includes data on PFOA and PFOS production-related waste. See U.S. Environmental Protection Agency. Toxic Release Inventory (TRI) Search. Available at: *https://www.epa.gov/enviro/tri-search.*

IV. Legal Authority

A. CERCLA Section 102(a) Designation Considerations

In this action, the Administrator is exercising his authority to designate PFOA and PFOS as hazardous substances pursuant to CERCLA section 102(a). CERCLA's definition of ''hazardous substances'' includes any substance designated pursuant to specified provisions in select environmental statutes (CWA, RCRA, CAA, and TSCA) and ''any element, compound, mixture, solution, or substance designation pursuant to [CERCLA section 102]. CERCLA section 101(14).[32] Section 102(a), in turn, provides clear authority to designate hazardous substances in addition to substances designated automatically through the operation of CERCLA section 101(14). In relevant part, section 102(a) provides that, ''[t]he Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances, in addition to those referred to in section 101(14), such elements, compounds, mixtures, solutions, and substances, which when released into the environment, may present substantial danger to the public health or welfare or the environment. . . .'' The statutory language delegates to EPA the authority to identify and weigh the scientific, technical, and other factual information relevant to determining whether a substance ''may present a substantial danger,'' and then determine whether to promulgate regulations designating such substances.

Reading Section 102(a) in context, including the broader context of CERCLA as a whole, EPA affirms the factors it proposed to evaluate for determining what constitutes ''substantial danger'' and designating hazardous substances under CERCLA section 102(a). 87 FR at 54421. To inform its decision whether a substance, when released, may present ''substantial danger'' pursuant to CERCLA section 102(a), EPA considers two primary factors: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance potentially moves, persists and/or changes when in the environment (*i.e.,* environmental fate and transport). EPA will then weigh this information in deciding whether the substance, when released, may present a substantial danger.

In deciding whether a substance presents potential harm to humans or the environment from exposure to the substance (hazard), EPA may consider such information as human health toxicity, including carcinogenicity, neurotoxicity, developmental toxicity, reproductive toxicity, and other adverse health effects. EPA may also consider toxicity or adverse impacts to non-human organisms or ecosystems, such as adverse effects to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas. Additionally, EPA may consider chemical properties such as combustibility, flammability, reactivity, or corrosiveness. Regarding the environmental fate and transport of a substance, EPA may consider whether a substance moves readily through the environment, and whether it persists and/or changes in the environment.

In weighing this information, EPA will consider the degree or magnitude of the danger posed based on the substance's hazard and environmental fate and transport characteristics. The hazard that a substance presents can be shown in a variety of ways. For example, it could be toxic to humans or other organisms in the environment, or it could exhibit a more physical hazard, such as corrosivity or explosivity.

In assessing a substance's hazard if based on toxicity, EPA could consider whether the substance may be acutely toxic (and thus lead to an immediate health problem or even death) or may have chronic toxicity (and thus lead to detrimental health effects after long-term exposure). For example, there could be a substance that is acutely toxic but does not move far from the point of release. This substance might pose substantial danger due to its ability to immediately harm people and other organisms at the point of release. As another example, there may be a substance that exhibits chronic toxicity and is very persistent. In this case, the substance might also pose substantial danger when released because people and other organisms near the point of release could be exposed to the substance over a long period of time, potentially leading to adverse health effects. Designation may be appropriate if the hazard and fate and transport, when taken together, demonstrate there may be danger and the danger is substantial.

Hazard and environmental fate and transport are the primary factors EPA will assess in evaluating whether to designate a substance under section 102(a). However, EPA may also consider additional information that could inform the degree of danger a substance may pose when released. This includes, but is not limited to, information such as frequency, nature, and geographic scope of releases (*e.g.,* prevalence) and likelihood of human exposure. For example, the Agency may review accident history or other release data (*e.g.,* TRI, UCMR) to determine how frequently a substance is released or found in the environment, and how or if the substance has caused any adverse health effects to the public or the environment. Together with hazard and environmental fate and transport, this additional information will inform EPA's conclusion on whether a substance, when released, may present a substantial danger to public health or welfare or the environment.

EPA interprets section 102(a) as requiring that, at a minimum, there is a possibility the substance, when released into the environment, presents substantial danger. EPA need not have certainty that the substance poses a substantial danger or require proof of actual harm when released into the environment. This reading of CERCLA section 102(a) is consistent with the ordinary meaning of ''may'' which is defined as a term ''used to indicate possibility or probability.'' Merriam-Webster (*https://www.merriam-webster.com/dictionary/may*). It is also consistent with the caselaw interpreting the term ''may'' in the phrase ''may present an imminent and substantial endangerment'' under RCRA, which has been construed as not requiring certainty. *See ME. People's Alliance* v. *Mallinckrodt, Inc.,* 471 F.3d 277, 288 (1st Cir. 2006) (noting that ''at least four of our sister circuits have construed [section 7002(a)(1)(B)] expansively'' and that ''all four courts have emphasized the preeminence of the word 'may' in

[32] The complete definition of ''hazardous substances'' is: ''(A) any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. 1321(b)(2)(A)], (B) any element, compound, mixture, solution, or substance designated pursuant to section 9602 of this title, (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921] (but not including any waste the regulation of which under the Solid Waste Disposal Act [42 U.S.C. 6901 *et seq.*] has been suspended by Act of Congress), (D) any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act [33 U.S.C. 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. 7412], and (F) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. 2606]. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).''

defining the degree of risk needed to support [section 7002(a)(1)(B)'s] liability standard'' and that certainty of harm is not required); *Price* v. *United States Navy,* 39 F.3d 1011, 1019 (9th Cir. 1994) (reasoning that the term ''may'' ''implies that there must be a threat which is present now, although the impact of the threat may not be felt until later'').

The information that EPA may consider in determining whether the release of a substance may present a substantial danger is consistent with the criteria that the Agency uses in implementing CERCLA through the Hazard Ranking System (HRS) (*U.S. EPA, 2023b*). CERCLA section 105(a)(8)(A) requires EPA to set criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial and removal action, to the extent practicable taking into account the potential urgency of such action. The statute directs EPA to develop criteria based upon relative risk or danger to public health or welfare or the environment, taking into account to the extent possible the population at risk, the hazard potential of the hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact, the potential for destruction of sensitive ecosystems, the damage to natural resources which may affect the human food chain and which is associated with any release or threatened release, and the contamination or potential contamination of the ambient air which is associated with the release or threatened release. EPA's regulations establishing criteria for placing sites on the National Priorities List are codified in EPA's Hazard Ranking System (HRS), 40 CFR part 300 App. A. Ultimately, the HRS factors are consistent with the information EPA considered in designating PFOA and PFOS under CERCLA section 102(a).

The standard that EPA has adopted for CERCLA section 102(a) is also consistent with EPA's interpretation of similar statutory language. *See, e.g.,* CERCLA section 104(a) (allowing for response to pollutants or contaminants that ''may present an imminent and substantial danger'') and CERCLA section 106(a) (granting enforcement authority ''when there may be an imminent and substantial endangerment'').[33] For example, CERCLA section 106(a) provides EPA with enforcement authority when ''there may be an imminent and substantial endangerment.'' EPA guidance provides that EPA should rely on ''scientific evidence and documentation'' to determine if conditions may present an imminent and substantial endangerment (*Breen et al., 2001*). This may include an evaluation of site-specific conditions that provide a ''reasonable cause for concern that someone or something may be exposed to a risk of harm by a release or a threatened release of a hazardous substance.'' *B.F. Goodrich Co.* v. *Murtha,* 697 F. Supp. 89, 96 (D. Conn. 1988). ''Hazard'' and ''fate and transport'' are inherently a part of that analysis, and courts have long examined such considerations under CERCLA section 106(a). *See, e.g., United States* v. *Northeastern Pharmaceutical and Chemical Co., Inc.,* 579 F. Supp. 823, 832 (W.D. Mo. 1984), aff'd in part, rev'd in part, 810 F.2d 726 (8th Cir. 1986) (examining toxicological properties, hazard, fate and transport, as well as likelihood of exposure in determining whether substances posed an ''imminent and substantial endangerment''); *United States* v. *E.I. du Pont de Nemours & Co., Inc.,* 341 F.Supp.2d 215, 247 (W.D.N.Y. 2004) (collecting cases and concluding endangerment exists where, examining all impacts, ''there is reasonable cause for concern that someone or something may be exposed to a risk of harm by a release or a threatened release''); *see also Cox* v. *City of Dallas, Tex.,* 256 F.3d 281, 300 (5th Cir. 2001) (examining hazard and fate and transport posed from dangerous gases in concluding that old landfill ''may present an imminent and substantial endangerment'' under RCRA).[34]

B. Consistency With Other Methodologies for Identifying CERCLA Hazardous Substances

The two central factors that EPA considers in the context of CERCLA section 102(a)—hazard, as well as fate and transport—are consistent with other methodologies used for identifying CERCLA hazardous substances. CERCLA's list of ''hazardous substances'' includes more than 800 substances identified as hazardous or toxic by Congress or EPA under the following specified environmental statutes:

- Clean Water Act section 311(b)(2)(A) hazardous substances;
- Resource Conservation and Recovery Act section 3001 hazardous wastes;
- Clean Water Act section 307(a) toxic pollutants;
- Clean Air Act section 112 hazardous air pollutants; and
- Toxic Substances Control Act section 7 imminently hazardous chemicals.

See 40 CFR Table 302.4 (list of hazardous substances).

EPA has applied these authorities in a manner similar to how EPA is interpreting and applying its authority under CERCLA section 102(a) in this action. For this designation, under section 102(a), EPA evaluated toxicity data to assess ''hazard'' from exposure to PFOA and PFOS. Similarly, the statutes cited in CERCLA's definition of hazardous substance consider toxicity in some fashion in their listing or identification decisions. *See* RCRA section 3001 (providing that EPA's criteria for listing RCRA regulated hazardous wastes take into account ''toxicity,'' along with other factors); CWA section 311(b)(2)(A) and 42 FR 10474, 10475 (March 13, 1978) (describing ''toxicological selection criteria'' for hazardous substances designated under the CWA section 311); CWA section 307(a) (providing CWA authority to list ''toxic pollutants'' taking into account ''toxicity of the pollutant''); CAA section 112(b)(2) (providing CAA authority to identify air toxics which ''present, or may present . . . a threat of adverse human health effects (including . . . substances which are known to be, or may reasonably be anticipated to be . . . acutely or chronically toxic)); TSCA section 7 (providing TSCA authority to identify a chemical substance or mixture as imminently hazardous when it ''presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other non-risk factors.'').

EPA also evaluated data regarding the fate and transport of PFOA and PFOS in the environment. This analysis focused primarily on the chemical and physical characteristics of PFOA and PFOS, including mobility, resistance to degradation, and persistence in the

[33] These provisions concern enforcement and response actions and apply to and require analysis of narrow, site-specific circumstances relevant to a particular facility or person, and to a specific event. As a result, the Agency conducts an assessment of the particular situation at each site when it invokes those other authorities. That purpose is distinct from the purpose of CERCLA section 102(a), which requires a more generalized, non-site-specific evaluation.

[34] CERCLA section 106 sets forth a site-specific standard, which differs from the general applicability of CERCLA section 102(a). The language between each section also slightly differs. The phrase ''imminent and substantial endangerment'' in section 106 is different from the phrase ''may present a substantial danger'' in section 102. However, given the similar language, the factors that courts have considered in analyzing whether a substance poses a threat under section 106 are instructive to determining whether a substance ''may pose a substantial danger'' under section 102.

environment. Similarly, the CWA, RCRA, and CAA provisions referenced in CERCLA, also consider persistence and resistance to degradation in their listing and identification decisions. *See* CWA section 307(a) (providing that EPA may list toxic pollutants under the CWA that take into account ''persistence and degradability,'' alongside toxicity); RCRA section 3001 (providing that EPA's criteria for listing RCRA regulated hazardous wastes take into account ''persistence and degradability in nature,'' along with other factors); CAA section 112(b)(2) (identifying ''bioaccumulation'' as a consideration for evaluating whether a pollutant may be identified as a hazardous air pollutant under CAA).

C. CERCLA Section 102(a) and Cost Considerations

EPA proposed interpreting CERCLA section 102(a) as precluding the consideration of cost in designating CERCLA hazardous substances. EPA recognizes that, as a general matter, a statutory assessment of health- and environmental-based criteria like the criteria in section 102 does not typically allow for consideration of costs. *See, e.g., Whitman* v. *American Trucking,* 531 U.S. 457, 471 (2001) (finding that public health criteria provided in the Clean Air Act, interpreted in its statutory and historical context and with appreciation for its importance to the CAA as a whole, unambiguously bars cost considerations.''). EPA is not resolving in this final action whether section 102 is best construed as precluding or requiring consideration of costs in designating a hazardous substance. It need not resolve this question here because designation is appropriate under either construction. Specifically, as discussed in Section V, examining only whether PFOA and PFOS may present a substantial danger to public health or welfare or the environment, without considering costs and benefits, EPA has concluded that designation is warranted. In addition to the analysis of the health- and environmental-based criteria, EPA also conducted a totality-of-the-circumstances analysis, including an evaluation of quantitative and qualitative benefits and costs of designation. This additional analysis confirmed that designation is appropriate. In sum, designation is warranted either by examining the health- and environmental-based criteria alone or by examining these criteria along with the broader totality of the circumstances.

V. PFOA and PFOS May Present a Substantial Danger to the Public Health or Welfare or the Environment When Released Into the Environment

In evaluating hazard with respect to PFOA and PFOS, EPA considered the substantial evidence, based on epidemiological and toxicological studies, indicating that human exposure to PFOA or PFOS is linked to adverse human health effects. Regarding environmental fate and transport, EPA considered evidence that PFOA and PFOS migrate through the environment from the point of release, that they persist in the environment for long durations, and that they bioaccumulate in humans and other organisms.

For PFOA and PFOS, EPA considered other relevant information about the frequency, nature, and geographic scope of releases of the substances (*i.e.,* prevalence) demonstrating that these substances have been widely detected in drinking water, surface water, wild animals, and humans in the United States. This other information about the prevalence of PFOA and PFOS is relevant to EPA's designation decision because widespread detections of these substances in the environment and people demonstrates a greater potential for communities to be exposed to the substances at concentrations that could result in adverse health effects. EPA weighed all of this information—hazard, environmental fate and transport, prevalence—in evaluating the degree or magnitude of danger posed. EPA concluded that PFOA and PFOS may present a substantial danger when released because of the potential for harm to human health, evidence of persistence and bioaccumulation, and high likelihood of exposure.

A. PFOA and PFOS Pose a Hazard

EPA is confirming the proposed finding that exposure to PFOA and PFOS may pose a hazard, after evaluating the available scientific and technical information as well as public comments. There is evidence from both epidemiological and animal toxicological studies that oral exposure to either PFOA or PFOS has been associated with various adverse health effects across many health outcomes. Numerous health studies support a finding that PFOA and PFOS exposure can lead to adverse human health effects, including cancer (testicular and kidney for PFOA, liver cancer for PFOS), pregnancy-induced hypertension and preeclampsia, and decreased immune response to vaccination (*ATSDR, 2021*). Toxicology studies suggest that PFOA and PFOS exposure is associated with decreases in serum thyroid hormone levels [35] and adverse effects to the endocrine system (ATSDR, 2021; USEPA, 2024b; 2024c).

Based on studies of PFOA and PFOS, in 2021, EPA found that PFOA and PFOS may have adverse effects on public health (''*Announcement of the Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List,'' 2021*). EPA determined that studies indicate human exposure to PFOA and/or PFOS is linked to a broad range of adverse health effects, including developmental effects to fetuses during pregnancy or to infants (*e.g.,* low birth weight, accelerated puberty, skeletal variations), liver effects (*e.g.,* tissue damage), immune effects (*e.g.,* antibody production and immunity), and other effects (*e.g.,* cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk or formula made with contaminated water. Both compounds were also associated with carcinogenic effects in human epidemiological and long-term animal studies (*NTP, 2020; U.S. EPA, 2016a, 2016b*). In November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2b) (Zahm, et al., 2023).

These adverse health effects of PFOA and PFOS were further described in the final toxicity assessments and Final Maximum Contaminant Level Goals (MCLGs [36]) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) in Drinking Water (*U.S. EPA, 2024b, 2024c, 2024d*). These toxicity assessments indicate that PFOA and PFOS are associated with adverse health effects at lower levels than previously recognized. In the final toxicity assessments, EPA assessed the weight of the evidence for the available cancer data and determined that PFOA and PFOS are *Likely to Be Carcinogenic to Humans* consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005*). For PFOA, this determination is based on

[35] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology (ATSDR, 2021; USEPA, 2024b; USEPA, 2024c).

[36] Maximum Contaminant Level Goal (MCLG)—the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. (*https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.*)

the evidence of kidney and testicular cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular adenomas in rats. (*U.S. EPA, 2024c, 2024d*). For PFOS, this determination is based on the evidence of hepatocellular tumors in humans and rats, pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans as described by U.S. EPA (*2024b, 2024d*).

The EPA's 2024 PFOA and PFOS toxicity assessments prioritized the following five health endpoint categories with the strongest weight of evidence and indicating that oral PFOA and PFOS exposure is associated with adverse health effects: immunological, hepatic, developmental, cardiovascular, and cancer effects. This prioritization was based on findings from conducting systematic review (including the study quality evaluation, evidence synthesis and evidence integration) on the available and relevant human epidemiological and animal toxicity studies (*U.S. EPA, 2024b, U.S. EPA, 2024c*). EPA evaluated sixteen non-cancer health outcomes as part of the 2024 toxicity assessments and, in accordance with recommendations from the SAB {U.S. EPA, 2022, 10476098} and the IRIS Handbook {U.S. EPA, 2022, 10367891}, EPA's toxicity assessments prioritized the five categories of health outcomes above with either *evidence demonstrating* or *evidence indicating* associations between PFOA and PFOS exposure and adverse health effects. Accordingly, to support EPA's finding in this final rule that both PFOA and PFOS each individually pose a human health hazard, EPA gave weight to immunological, hepatic, developmental, cardiovascular, and cancer effects.

For this final rule, EPA considered a wide range of potential health effects associated with exposure to PFOA and PFOS using five comprehensive peer-reviewed Federal government documents that summarize the recent literature on PFAS (mainly PFOA and PFOS) exposure and its health impacts: (1) EPA's 2016 Health Effects Support Documents for PFOA *(U.S. EPA, 2016c)*; (2) EPA's 2016 Health Effects Support Documents for PFOS (*U.S. EPA, 2016d)*; (3) U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry's (ATSDR) 2021 Toxicological Profile for Perfluoroalkyls (*ATSDR, 2021)*; (4) EPA's 2024 Final Human Health Toxicity Assessment for Perfluorooctanoic Acid *(PFOA)* (*U.S. EPA, 2024b*); and (5) EPA's 2024 Final Human Health Toxicity Assessment for Perfluorooctane Sulfonic Acid (PFOS), (*U.S. EPA, 2024c*). Each source presents comprehensive, systematic reviews of relevant, peer-reviewed literature on adverse health effects associated with PFOA and PFOS. The EPA assessments were prepared by the Office of Water.

Data from human and animal studies indicate that PFOA and PFOS are well absorbed in the human body after being ingested and are distributed throughout the body by binding to proteins. PFOA and PFOS bioaccumulate in the human body as evidenced by the elimination half-lives from about two to three years for PFOA and four to five years for PFOS (*ATSDR, 2021*). There is no evidence that humans or animals are able to break down these substances, and they can be distributed to tissues throughout the human body and are not readily eliminated, resulting in long elimination half-lives in the human body and bioaccumulation. Available evidence supports urine as the primary route of excretion in most species, though fecal elimination is prominent in rats. In rats, hair is another route of elimination in both males and females. In females, elimination pathways include menstruation, pregnancy (cord blood, placenta, amniotic fluid, and fetal tissues) and lactation (breast milk) (PFOA Toxicity Assessment 2024, PFOS Toxicity Assessment 2024). Thus, PFOA and PFOS remain in the body after exposure has ended and can potentially cause detrimental health effects even after an initial exposure has ceased. Continued exposures to PFOA and PFOS can lead to significantly elevated concentrations in the human body and result in adverse health effects due to this bioaccumulation (Ballesteros et al., 2017; Barry et al., 2014; Dhingra et al., 2016; Frisbee et al., 2010; Gallo V et al., 2012; Hall et al., 2023; Hoffman et al., 2011; Kotlarz et al., 2020; Savitz et al., 2012; Steenland et al., 2009; Steenland et al., 2018a; Steenland et al., 2018b).

EPA's 2024 Final Human Health Toxicity Assessments for PFOA and PFOS integrated the available data on absorption, distribution, metabolism and elimination into the derivation of reference values for PFOA and PFOS. Collectively the adverse health effects evidence demonstrates that each PFOA and PFOS individually pose a human health hazard, and the substantial body of evidence for several individual adverse health effects also supports EPA's human health hazard finding for each of these substances. A discussion of some of the detrimental health effects follows.

Developmental Effects: Adverse developmental effects can increase the likelihood of difficulties during labor through post-delivery. Evidence indicates that exposure to PFOA and PFOS is likely associated with developmental effects such as lower infant birth weight, lower birth length, smaller head circumference at birth, and other effects (Verner et al., 2015; U.S. EPA, 2016e; U.S. EPA, 2016f; Negri et al., 2017; ATSDR, 2018; Waterfield et al., 2020; U.S. EPA, 2023b; U.S. EPA, 2024c). Research suggests that exposure to PFOA and PFOS is associated with developmental effects, including decreased infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (*Behrman & Rosenzweig, 2004; Chaikind & Corman, 1991; Colaizy et al., 2016; Institute of Medicine, 2007; Joyce et al., 2012; Klein & Lynch, 2018; Kowlessar et al., 2013; Nicoletti et al., 2018*).

Toxicity studies conducted in laboratory animal models demonstrate that the developing fetus is particularly sensitive to PFOA- and PFOS-induced toxicity. Some studies in laboratory animals indicate that gestation and/or lactation periods are critical exposure windows that may lead to developmental health effects including decreased offspring survival, low birth weight, accelerated puberty and skeletal variations (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*). The embryo and fetus are exposed prenatally to PFOA and PFOS through maternal blood via the placenta (*ATSDR, 2021*). Several epidemiological studies of the association between maternal serum PFOA/PFOS and birth weight have found evidence for decreased body weight of infants exposed in utero (*Chu et al., 2020; Darrow et al., 2013; Dzierlenga et al., 2020; Govarts et al., 2016; Negri et al., 2017; Sagiv et al., 2018; Starling et al., 2017; Verner et al., 2015; Wikstrom et al., 2020; Yao et al., 2021*). Other developmental associations with PFOA and PFOS include small for gestational age (SGA), decreased birth length, decreased head circumference at birth, and other effects (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Epidemiology evidence for SGA related to PFOA/PFOS exposure was mixed; some studies reported increased risk of SGA with PFOA/PFOS exposure, while other studies observed null results (USEPA,

2024b; USEPA, 2024c). SGA is a developmental health outcome of interest when studying potential effects of PFOA/PFOS exposure because SGA infants have increased health risks during pregnancy and delivery as well as post-delivery (*Osuchukwu & Reed, 2022*).

Cardiovascular Effects: Cardiovascular Disease (CVD) is one of the leading causes of premature mortality in the United States (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). Changes in total cholesterol and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.,* heart attack), ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). Evidence indicates that exposure to PFOA and PFOS is likely associated with increased low-density lipoprotein cholesterol (LDLC), total cholesterol, and high-density lipoprotein cholesterol (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). High levels of LDLC lead to the buildup of cholesterol in the arteries, which can raise the risk of heart disease and stroke. Epidemiology studies showed a positive association between PFOA or PFOS exposure and LDLC or total cholesterol levels in children (*U.S. EPA, 2024b, 2024c*). In particular, the evidence suggested positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18, while positive associations between serum levels and LDLC levels in younger children were observed only for PFOA (*ATSDR, 2021*). Other epidemiology studies have generally found a positive association between increasing serum PFOA and total cholesterol levels (*ATSDR, 2021*).

Cancer Effects: PFOA and PFOS are Consistent with the Guidelines for Carcinogen Risk Assessment (*U.S. EPA, 2005*), EPA determined that both PFOA and PFOS are *Likely to Be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (U.S. EPA, 2024b, USEPA 2024c). Additionally, in November 2023, the International Agency for Research on Cancer (IARC) evaluated the carcinogenicity of PFOA and PFOS and classified PFOA as carcinogenic to humans (Group 1) and PFOS as possibly carcinogenic to humans (Group 2b) (Zahm, et al., 2023). For PFOA, cancer evidence in epidemiological studies is primarily based on the incidence of kidney and testicular cancer, as well as some evidence of breast cancer, which is most consistent in genetically susceptible subpopulations or for particular breast cancer types (*U.S. EPA, 2024c*). Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of renal cell carcinoma (RCC) (*ATSDR, 2021; California EPA, 2021; U.S. EPA, 2016d, 2024d*). For PFOS, the available epidemiology studies report elevated risk of liver cancer, consistent with increased incidence of liver tumors reported in long-term rat exposure studies. There is also mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans after chronic exposure and evidence of pancreatic islet cell tumors in rats (*U.S. EPA, 2024b*).

Liver Effects: High levels of the enzyme alanine transaminase (ALT) in the bloodstream may indicate liver damage. Evidence indicates that exposure to PFOS and PFOA is associated with increased liver enzymes (U.S. EPA, 2024b; 2024c). Epidemiology data provides evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Studies of adults showed consistent evidence of a positive association between PFOA exposure and elevated ALT levels at both high exposure levels and exposure levels typical of the general population (*U.S. EPA, 2024c*). Associations between increasing serum PFOA concentrations and elevations in different serum enzyme levels were consistently observed in occupational cohorts, high-exposure communities and the U.S. general population that could indicate the potential for PFOA to affect liver function (*ATSDR, 2021*). There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels. A limited number of studies reported inconsistent evidence on whether PFOA/PFOS exposure is associated with increased risk of liver disease (*U.S. EPA, 2024b*). Results reported in animal toxicological studies are consistent with the observed elevated ALT indicative of hepatic damage in epidemiological studies. Specifically, studies in rodents found that oral PFOA or PFOS treatment resulted in biologically significant alterations in levels of at least one serum biomarker of liver injury (*e.g.,* ALT) and evidence of histopathological alterations including hepatocyte degenerative or necrotic changes.

Immune Effects: Proper antibody response helps maintain the immune system by recognizing and responding to antigens. Evidence indicates that exposure to PFOS and PFOA is associated with immunosuppression; (U.S. EPA, 2024b; U.S. EPA, 2024c); epidemiology studies showed suppression of at least one measure of the antibody response for tetanus and diphtheria among people with higher prenatal, childhood, and adult serum concentrations of PFOA (*U.S. EPA, 2024c*). Data reporting associations between PFOA exposure and antibody response to vaccinations other than tetanus and diphtheria are limited (*ATSDR, 2021; USEPA, 2024c*). Several epidemiological studies have shown a relationship between increased PFOA and PFOS serum concentrations and decreased response to vaccinations in children (*Budtz-Jorgensen & Grandjean, 2018; Grandjean et al., 2012; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, & Budtz-Jorgensen, 2017; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, Timmermann, et al., 2017; Timmermann et al., 2022; Zhang et al., 2023*). Epidemiology evidence suggests that children with preexisting immunological conditions are particularly susceptible to immunosuppression associated with PFOA exposure (*U.S. EPA, 2024c*). Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum levels were associated with decreased antibody production (*U.S. EPA, 2024b*). Studies reporting associations between PFOA or PFOS and immunosuppression in adults are less consistent; there is a lack of high confidence data. (*U.S. EPA, 2024b*).

In addition to the adverse health effects listed above, there was suggestive evidence that exposure to PFOS and PFOA is associated with the additional health effects summarized below.

Endocrine Effects: Elevated thyroid hormone levels can accelerate metabolism and cause irregular heartbeat; low levels of thyroid hormone can cause neurodevelopmental effects, tiredness, weight gain, and increased susceptibility to the common cold. There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Toxicology studies in animals indicated that PFOA and PFOS exposure can affect thyroid function [37] (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Changes to serum thyroid hormone levels in animals lead to adverse effects to the endocrine system (*U.S. EPA, 2024b, 2024c*). Despite uncertainty around the applicability of animal studies in this area, changes in serum

[37] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*).

thyroid hormone levels in animals did indicate adverse effects after PFOS and PFOA exposure that is relevant to humans (U.S. EPA, 2024b; 2024c).

Metabolic Effects: Leptin is a hormone that controls hunger, and high leptin levels are associated with obesity, overeating, and inflammation (*e.g.,* of adipose tissue, the hypothalamus, blood vessels, and other areas). Animal studies showed increases in serum leptin levels in mice that were exposed to low levels of PFOA (ATSDR, 2021). Based on a review of 69 human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears inconsistent, but in some studies, suggestive evidence was observed between PFOS exposure and leptin levels (*U.S. EPA, 2024b*).

Reproductive Effects: Studies of the reproductive effects from PFOA/PFOS exposure have focused on associations between exposure to these pollutants and increased risk of gestational hypertension and preeclampsia in pregnant women (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). Gestational hypertension (high blood pressure during pregnancy) can lead to fetal health outcomes such as poor growth and stillbirth. Preeclampsia—instances of gestational hypertension where the mother also has increased levels of protein in her urine—can similarly lead to fetal problems and maternal complications. The epidemiology evidence yields mixed (positive and non-significant) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). A study of a community with high exposure to PFOA observed an association between serum PFOA and risk of pregnancy-related hypertension or preeclampsia, conditions that are related to renal function during pregnancy (*U.S. EPA, 2016d*).

Musculoskeletal effects: Adverse musculoskeletal effects such as osteoarthritis and decreased bone mineral density impact bone integrity and cause bones to become brittle and more prone to fracture. There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis (*U.S. EPA, 2024b*). Epidemiology evidence suggested that PFOA exposure may be linked to decreased bone mineral density, bone mineral density relative to bone area, height in adolescence, osteoporosis, and osteoarthritis (*ATSDR, 2021; U.S. EPA, 2024c*). Evidence from four PFOS studies suggests that PFOS exposure has a harmful effect on bone health, particularly measures of bone mineral density, with greater statistically significance of effects occurring among females (*U.S. EPA, 2024b*).

Taken together, the technical/scientific information above demonstrate that both PFOA and PFOS individually are each associated with considerable and varied adverse health effects.

EPA also considered potential effects on children's health. EPA's Policy on Children's Health requires the Agency to consider early life exposures (from conception, infancy, early childhood and through adolescence until 21 years of age) and lifelong health consistently and explicitly in all human health decisions through identifying and integrating children's health data and information. As described throughout this section, information on PFOA and PFOS shows exposure to PFOA and/or PFOS is linked to adverse health effects relevant to children. These adverse health effects include developmental effects to fetuses during pregnancy or to infants, cardiovascular effects and immune effects in children and endocrine and reproductive effects that impact development. Suggestive evidence of associations found in human epidemiological studies between PFOA and PFOS and adverse development effects of include decreased infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 2024b, 2024c; Verner et al., 2015; Waterfield et al., 2020*). Animal studies have shown developmental health effects including associations with decreased offspring survival, low birth weight, accelerated puberty and skeletal variations (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*). Cardiovascular effects include positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18 (*ATSDR, 2021*). Several epidemiological studies have shown a relationship between increased PFOA and PFOS serum concentrations and decreased response to vaccinations in children (*Budtz-Jorgensen & Grandjean, 2018; Grandjean et al., 2012; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, & Budtz-Jorgensen, 2017; Grandjean, Heilmann, Weihe, Nielsen, Mogensen, Timmermann, et al., 2017; Timmermann et al., 2022*). There is suggestive evidence of a positive association between PFOA and/or PFOS exposure and thyroid hormone disruption (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*). The epidemiology evidence yields mixed (positive and non-significant) associations, with some evidence suggesting positive associations between PFOA and/or PFOS exposure and both preeclampsia and gestational hypertension which can lead to fetal health outcomes such as poor growth, stillbirth and maternal complications (*ATSDR, 2021; U.S. EPA, 2024b, 2024c*).

EPA also considered the hazards associated with salts and structural isomers of PFOA and PFOS. The hazards associated with PFOA and PFOS can be associated with their respective salts and both their linear and branched isomers. Salts are deemed to have the same toxicity as the commonly referenced acid versions because, once put in water (and likewise when in the human body), the acid and salt forms will dissociate to the ionic form. Further, many toxicity studies on PFAS were often performed using the salt form. For example, while *Emmett et al.* (*2006*) toxicity studies were performed on the acid version of PFOA, *Butenhoff et al.* (*2012*) used the ammonium salt of PFOA. The potassium salt of PFOS was generally used in animal toxicity studies such as *Ankley et al.* (*2004*).

Additionally, PFOA and PFOS exist as linear and branched isomers, and the linear and branched isomers have been found in environmental media and in human sera. For example, in the last NHANES for which results are available (*2017–2018*), branched PFOS was detected in 99% of those sampled, while branched PFOA was found in 10%. Most animal toxicity studies using isomeric mixtures do not state the ratio of linear and branched isomers in the test material, and, therefore, it is not feasible to distinguish the toxicity of the individual isomers. However, in a few studies, including *Butenhoff et al.* (*2012*), *Lau et al.* (*2006*), and *Lou et al.* (*2009*) for PFOA, and *Ankley et al.* (*2004*) for PFOS, the authors stated that the PFAS test substance was not 100% linear, and thus, any effects indicated in these studies can only be associated with the isomeric mixture of linear and branched and not specifically with linear isomers or branched isomers. Further, *Loveless et al.* (*2006*) compared the toxicity of linear ammonium PFOA, branched ammonium PFOA, and a mixture of linear and branched ammonium PFOA in rodents and demonstrated that both linear and branched isomers exhibit similar types of toxicity.

B. Information About the Fate and Transport of PFOA and PFOS Demonstrate That They Are Persistent and Mobile in the Environment

Available information about the fate and transport of PFOA and PFOS

support EPA's conclusions that these substances remain in the environment for many years (*i.e.,* persistency) and that they can move through air, land, and water (*i.e.,* mobility) after release. Both PFOA and PFOS are considered surfactants due to their chemical structures that consists of a hydrophobic perfluorinated alkyl ''tail group'' and a hydrophilic carboxylate (for PFOA) or sulfonate (for PFOS) ''head group.'' Surfactants decrease the surface tension between two liquids (*i.e.,* oil and water), a gas and a liquid, or a solid and a liquid. This attribute means they increase mixing and transport between soil and groundwater or air and water, and thus PFOA and PFOS move between environmental media more easily.

These chemicals are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause PFOA and PFOS to be extremely resistant to degradation through biological degradation and also through chemical degradation (*i.e.,* photooxidation and hydrolysis). Photooxidation describes the process of oxidation through light exposure and hydrolysis describes the chemical breakdown of compound due to reaction with water. Degradation data from 3M for PFOA states ''Hydrolysis half-life >92 years @ pH 7 & 25 °C (ammonium salt tested); Photolysis in water: half-life > = 342 days; neither direct nor indirect photolysis in water observed based on loss of PFOA; Biodegradation-OECD 301C, 28 days, 5% BOD/ThOD; Biodegradation-Aerobic sludge, 18 days, no degradation observed (ammonium salt tested); Biodegradation-Anaerobic sludge, 94 days, no degradation observed.'' Degradation date from 3M for PFOS states ''Biodegradation-Anaerobic sludge, 105 days, no degradation observed; Biodegradation-OECD 301C (MITI–I), 28 days, 0% BOD/ThOD (3M 2021).'' The resistance to degradation causes PFOA and PFOS to remain in the environment for long periods of time. This means that the potential for human exposure continues long after a release has ended.

PFAS are mobile in the environment and have been found in remote locations, indicating they are widespread in the environment (*Giesy & Kannan, 2001*). PFAS have been found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean (*ATSDR, 2021*). PFOA and PFOS are water soluble and thus may be found in groundwater and surface water (*U.S. EPA 2024a*). Further, PFOA and PFOS have water-soil/sediment partition coefficients of 15–708 L/kg and 7–120 L/kg, respectively (*3M, 2021*). These values are on the order of many metals, indicating that PFOA and PFOS are fairly mobile and will move from soil and sediment to water. Experimental data indicates in the marine environment, where suspended solid concentrations are generally low, PFOA and PFOS are mainly transported in the dissolved phase rather than being adsorbed to suspended solids (*Ahrens et al., 2011*). Their presence in the water column means that they will be transported further and are available for long range transport and bioaccumulation (*Ahrens et al., 2011*).

In a 2001 study investigating the global distribution of PFAS, wildlife samples were collected on four continents including North America and Antarctica and PFAS was found to be widely distributed on a global scale.[38 39] Over 30 different species had measurable levels of PFOS (*European Food Safety Authority, 2008; Giesy & Kannan, 2001*). PFOA and PFOS have been shown to persist in humans and animals, with estimated half-lives in humans ranging from about two to three years for PFOA to four or five years for PFOS (*ATSDR, 2021*). Organisms that are exposed to PFOA and PFOS cannot break them down inside the body and excrete very little. Because PFOA and PFOS can remain in human and animal bodies for long durations, individuals with consistent ongoing exposures to PFOA and PFOS (*e.g.,* individuals consistently exposed by drinking contaminated water or eating contaminated food) can have elevated concentrations of these substances in their bodies (*Bangma et al., 2017; Burkhard, 2021; Ng & Hungerbuhler, 2014*).

C. Other Information Considered

Other information that EPA considered includes, the frequency, nature, and geographic scope of releases of these substances. This information demonstrates that PFOA and PFOS are prevalent, including in the U.S., and there is likelihood of exposure to humans and the environment. PFOA and PFOS are prevalent throughout the environment because of their widespread use since the 1940s in a wide range of commercial and consumer products and because of their persistence. Currently, the public can be exposed to PFOA and PFOS through a variety of sources, including water, food, and environmental media. *See Proposed Rule, 87 FR at 54418–19* (Discussion on the uses of PFOA and PFOS).

Major causes of PFOA and PFOS environmental contamination include historical uses, limited ongoing uses, and ongoing uses of precursors. These activities include past direct industrial discharges of PFOA and PFOS to soil, air, and water and disposal of these substances or products that contain these substances. Precursor chemicals can also degrade to PFOA and/or PFOS (*e.g., perfluorooctanesulfonamide (PFOSA) can be transformed to PFOS in the environment*). PFOA and PFOS precursors can be converted to PFOA and PFOS, respectively, by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. *See Proposed Rule, 87 FR at 54426* (providing a brief history of sources of PFOA and PFOS to the environment).

PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. The most vulnerable drinking water systems are those in close proximity to sites contaminated with PFOA and PFOS (*ATSDR, 2021*). Under the third Unregulated Contaminant Monitoring Rule (UCMR), EPA worked with the States and local communities to monitor for six PFAS, including PFOA and PFOS, to understand the nationwide occurrence of these chemicals in the U.S. drinking water provided by public water systems (PWSs). Of the 4,920 PWSs with results for PFOA and PFOS, PFOA was detected above the minimum reporting level (minimum reporting level = 20 nanogram/liter (ng/L)) in 379 samples in 117 PWSs serving a population of approximately 7.6 million people located in 28 States, Tribes, or U.S. territories. PFOS was found in 292 samples at 95 systems above the UCMR 3 MRL (40 ppt). These systems serve a population of approximately 10.4 million people located in 28 States, Tribes, or U.S. territories (*U.S. EPA, 2017*).

More recent available data collected by States show continued occurrence of PFOA and PFOS in drinking water supplies in multiple geographic locations throughout the country, as well as occurrences at lower concentrations and significantly greater frequencies than were measured under the UCMR3 (''*PFAS National,*'' *2023*). PFOA and PFOS are also widely detected in surface water samples

[38] Global Distribution of Perfluorooctane Sulfonate in Wildlife; John P. Giesy and Kurunthachalam Kannan; Department of Zoology, National Food Safety and Toxicology Center, Institute for Environmental Toxicology; Michigan State University.

[39] *https://www.efsa.europa.eu/en/efsajournal/pub/653.*

collected from various rivers, lakes, and streams in the United States. Municipalities and other entities may use surface water sources for drinking water and that creates an additional potential exposure pathway to PFOA and PFOS.

PFOA and PFOS can reach soil due to atmospheric transport and wet/dry deposition (*ATSDR, 2021*). These substances have been found in outdoor air at locations across the globe around PFAS production facilities and facilities that use PFAS. PFOA and PFOS have been detected in surface and subsurface soils. Levels of PFOA and PFOS generally increased with increasing depth at sampled locations (PFAS manufacturing facilities), suggesting a downward movement of the contaminants and the potential to contaminate groundwater (*ATSDR, 2021*).

PFOA and PFOS can be taken up by plants, as evidenced by their presence in produce analyzed by the U.S. Food and Drug Administration (*2021*). PFOA and PFOS have also been found in wild and domestic animals such as fish, shellfish, alligators, deer, and avian eggs and in humans (*ATSDR, 2021*). For example, PFOA has been found in snack foods, vegetables, meat dairy products and fish, and PFOS has been found in eggs, milk, meat, fish and root vegetables (*Bangma et al., 2017; Falk et al., 2012; Gewurtz et al., 2016; Holmstrom et al., 2005; Michigan PFAS Action Response Team, 2021; Morganti et al., 2021; U.S. EPA, 2016a, 2016b; Wang et al., 2008; Wisconsin DNR, 2020*).

There is a significant potential for human exposure to PFOA or PFOS because of their persistence, mobility, and prevalence in the environment (*Langenbach & Wilson, 2021*). PFOA and PFOS contamination in the environment can lead to human exposure through ingestion of contaminated water, plants, wild animals, and livestock. PFOA and PFOS enter the drinking water supply from contamination in groundwater and surface water sources for drinking water. Contaminated drinking water or groundwater can also be used to irrigate or wash home-grown foods or farm-grown foods, thereby providing another means for human exposure. Human exposure can occur through the consumption of wild animals that have been contaminated by environmental exposure. Several States have issued advisories recommending that hunters and fishers avoid eating deer, turkey, or fish due to high levels of PFOS detected in the animals (*MDIFW, 2023; Michigan PFAS Action Response Team, 2023; NCDHHS, 2023*). Contaminated water also results in the contamination of livestock such as beef, pork, poultry, etc. Susceptible populations, such as women of reproductive age, pregnant and breastfeeding women, and young children who eat fish may have increased exposure to PFOA and PFOS due to bioaccumulation in fish (*Christensen et al., 2017; FDA, 2021; U.S. EPA, 2019b*). Food can also be contaminated through food packaging made with these chemicals. However, in 2016, the Food and Drug Administration revoked the regulations authorizing the remaining uses of long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016, and 81 FR 83672, November 22, 2016). Therefore, PFOA and PFOS should not be in food packaging now. Humans can also be exposed through incidental ingestion of contaminated soil and dust. Numerous studies have shown that PFOA and PFOS can be found in residences, offices, and other workplaces, and in consumer goods (*Gaines, 2023; Hall et al., 2020; Strynar & Lindstrom, 2008*).

PFOA and PFOS have been detected in nearly all of the blood of the participants in the NHANES. This indicates widespread exposure to these PFAS in the U.S. population (*CDC, 2022*). As part of the continuous NHANES, PFOA and PFOS were measured in the serum of a representative sample of the U.S. population ages 12 years and older in each two-year cycle of NHANES since 1999–2000, with the exception of 2001–2002. PFOA and PFOS have been detected in 99% of those surveyed in each NHANES cycle. As of the 2017–2018 data, PFOA and PFOS were still detectable in 99% of the population, although the mean concentrations of PFOA and PFOS in the serum have been steadily decreasing since 1999–2000 (*CDC, 2021; U.S. EPA, 2019a*).

Communities drinking water or eating food contaminated with PFAS can have significantly elevated blood levels of PFAS compared to national average concentrations (*Graber et al., 2019; Kotlarz et al., 2020*). Because PFOA and PFOS can remain in the human body and for long durations, individuals who have consistent ongoing exposures to PFOA and PFOS (*e.g.,* those exposed by drinking contaminated water or eating contaminated food) can have high concentrations of these compounds in their bodies. Epidemiological studies measuring PFAS levels in humans have noted that people living near contaminated sites have higher concentrations of these chemicals than the general population and that drinking water is an important contributor to exposure (*Emmett et al., 2006*).

Conclusion

In light of the evidence regarding hazard and the fate and transport of these chemicals, and consideration of the degree or magnitude of danger posed, EPA concludes for several reasons described above that PFOA and PFOS each may present a substantial danger when released into the environment.[40] Furthermore, the other information EPA considered, such as environmental prevalence and the likelihood of exposure, reinforce its conclusion. individuals living in communities located near sites with high levels of PFOA and PFOS (*e.g.,* sites where PFOA and PFOS were manufactured or used in the manufacture of products) are the populations (*i.e.,* non-occupationally exposed populations) most likely to be exposed to PFOA or PFOS and are thus more likely to experience associated adverse health effects.

At the same time, the mobility of PFOA and PFOS means that these substances have the potential to migrate away from a highly contaminated site into sources of drinking water, both groundwater and surface water. And the mobility and persistence combine to create an ever-expanding area of contamination if it is not contained and/or cleaned up. The persistence, mobility, and prevalence of PFOA and PFOS create more opportunities for exposure to humans and the environment, thereby increasing the likelihood of adverse health effects and adverse ecological burdens stemming from the toxicity of these compounds. *See Proposed Rule, 87 FR 54415.* In sum, communities located near sites with the highest concentrations of PFOA and PFOS are subject to a disproportionately higher risk of exposure to those substances as compared to the general population.

For all these reasons, EPA finds that both PFOA and PFOS, and their salts and isomers, each may present a substantial danger to the public health, or welfare, or the environment when released.

[40] EPA need only determine that PFOA and PFOS ''may present'' a substantial danger to designate as hazardous substances pursuant to CERCLA. CERCLA section 102(a). Other actions taken by EPA, pursuant to other statutory authorities, may require a different or more stringent finding. The scientific and technical data that EPA is relying on in this action may be relevant to those determinations and may support a finding under a more stringent standard.

VI. The Totality of the Circumstances Confirms That Designation of PFOA and PFOS as Hazardous Substances Is Warranted

Along with concluding that both PFOA and PFOS ''may present a substantial danger,'' EPA also independently exercised its discretion and conducted an additional ''totality of the circumstances'' analysis to evaluate whether designation was warranted. The analysis looks to the evidence showing that PFOA and PFOS ''may present a substantial danger'' along with CERCLA section 102(a) and its broader context. CERCLA section 102(a) and its broader context help identify the information to weigh and how to balance multiple considerations. In conducting the analysis as to PFOA and PFOS, EPA identified and weighed the advantages and disadvantages of designation. This analysis included consideration of the formal benefit-cost analysis, including quantitative and qualitative benefits and costs provided in the Regulatory Impact Analysis accompanying this final rule.

The totality of the circumstances analysis first considered the evidence that both PFOA and PFOS may present a substantial danger to public health or welfare or the environment when released, *see* CERCLA section 102(a). Specifically, EPA examined the scientific basis for designation. EPA gave the scientific evidence considerable weight. As discussed in Section V above, PFOA and PFOS exposure has been connected to a wide range of adverse human health and environmental effects. PFOA and PFOS bioaccumulate in humans and animals, including the fish and other wild animals we eat. And PFOA and PFOS are persistent and mobile in the environment. If not addressed, PFOA and PFOS will continue to migrate, further exacerbating exposure risk and potential cleanup costs.

EPA then evaluated CERCLA section 102(a) in the broader context of CERCLA. Section 102(a) provides EPA with health- and environmental-based criteria to evaluate whether a substance can be designated as hazardous. A hazardous substance designation, in turn, makes available the full suite of CERCLA authorities. EPA examined the ways in which designation serves CERCLA's express purposes and functions: ensuring that the ''Polluter Pays'' for cleanup (CERCLA sections 107(a), 106(a)); allowing for timely cleanup of contaminated sites (CERCLA sections 104, 106, 121); and authorizing response that protects human health and the environment (CERCLA sections 104, 106, 121).

With these statutory purposes in mind, EPA considered the core problem posed by PFOA and PFOS in the environment and whether designating PFOA and PFOS as hazardous substances would meaningfully improve EPA's ability to address the problem. EPA believes that the likelihood of the public being exposed to PFOA and PFOS is high. The science demonstrates that human exposure to these chemicals is linked to a broad range of adverse health effects. These concerns apply particularly to those communities living near former manufacturing sites, where PFOA and PFOS were produced (and then widely used) since the 1940s. As a result, communities may be exposed to existing contamination at and near sites where those substances were manufactured and used for decades. These contaminated sites have the potential to disproportionately harm nearby communities and ecosystems. Because of this potential risk, such sites need to be investigated, evaluated for risk to human health and the environment, and cleaned up as appropriate. EPA concluded that CERCLA is best suited to address the problem posed by legacy PFOA and PFOS contamination.

EPA next considered whether the hazardous substances designation is warranted considering EPA's existing authority that allows the Agency to address PFOA and PFOS as CERCLA ''pollutants and contaminants.'' EPA weighed how designation may promote cleanups that might otherwise be delayed or not occur. EPA's current authority to is limited in meaningful ways.[41] This rule, however, will allow EPA to utilize the full suite of CERCLA authorities and enable EPA to address more sites, allow for earlier action, and expedite eventual cleanup. This is, in large part, because EPA will be able to employ CERCLA's liability and enforcement provisions to require parties responsible for significant pollution to address existing contamination. As a consequence, designation greatly expands societal resources available (both financial and human capital) for investigation and cleanup that would not be available absent designation.

EPA also weighed the quantitative and qualitative costs and benefits evaluated in the RIA.[42] EPA considered the estimated direct and indirect monetized costs. These costs include direct costs to comply with release notification requirements and indirect costs for response actions, including potential costs for existing and future NPL sites as well as potential costs that may arise from enforcement actions taken at non-NPL sites. EPA also considered qualitative costs, which are those that EPA could not quantify with reasonable certainty. Qualitative costs encompass the potential costs of litigation and liability. Although EPA was unable to quantify these potential costs, EPA evaluated how designation may affect CERCLA liability and litigation. EPA analyzed whether CERCLA's statutory provisions (*e.g.,* liability limitations, cost recovery provisions and settlement authorities) and existing enforcement discretion policies could mitigate those potential costs. Next, in evaluating benefits, EPA considered the quantified baseline benefits associated with transferring response costs from EPA to PRPs as well as quantified health benefits that may result from the designation. These health effects include those associated with birth weight, cardiovascular disease (CVD) and renal cell carcinoma (RCC)-avoided morbidity and mortality associated with reductions in PFOA and/or PFOS. Unquantified health benefits include health effects such as immune, liver, endocrine, metabolic, reproductive, musculoskeletal, as well as certain cancers such as combined hepatocellular adenomas and carcinomas.

EPA also considered the ways in which the accompanying RIA does not fully capture the quantitative costs or benefits of the rule due to data limitations. As discussed throughout this preamble, CERCLA response actions are discretionary, contingent, and site-specific determinations. Whether it is appropriate to take any action—such as through CERCLA

---

[41] As described in Section II.E., CERCLA authority differs with respect to ''hazardous substances'' and ''pollutants or contaminants.'' Designation of PFOA and PFOS as ''hazardous substances'' streamlines response authority, makes available cost recovery authorities allowing parties to recover response costs from PRPs, and makes available CERCLA enforcement authority to compel PRPs to conduct or pay for cleanup. *See* CERCLA sections 104(a), 106(a), 107(a). Designation also requires facilities to notify federal, state, local, and tribal authorities, as well as potentially injured parties, of significant releases. *See* CERCLA sections 103(a), 111(g); EPCRA section 304.

[42] EPA conducted a Regulatory Impact Analysis (RIA) consistent with E.O. 12866. The E.O. requires, among other things, that the Agency quantify costs and benefits to the extent possible and that it qualitatively address the costs and benefits that cannot be quantified. The analyses required under the E.O. do not determine the appropriate consideration of advantages and disadvantages for EPA final actions. Instead, the EPA statute, in this case CERCLA, must be evaluated to determine the intended benefits of the statute as determined by it terms.

response authority under section 104 or CERCLA enforcement authority under section 106—is based on a myriad of factors and most importantly whether the releases at the site pose unacceptable risk. Because EPA cannot fully assess and characterize the magnitude and number of instances where the rule would reduce impacts associated with PFOA or PFOS exposure, the benefits are difficult to fully ascertain and estimate with certainty. In addition, there is considerable uncertainty regarding the cost of health burdens that may result from exposure to PFOA or PFOS, and associated cost savings from reducing the incidence of these burdens because of designation.

Relatedly, future response costs are also difficult to quantify due to the site-specific nature of CERCLA. Unlike with benefits, though, EPA concluded that it has sufficient information to reasonably estimate anticipated future costs for NPL and non-NPL sites. EPA was able to utilize existing data to estimate a high and low range for response costs at these sites. As explained in Section VI.A, the investigative and remedial technologies available to address PFOA and PFOS are, in large part, the same remedial technologies used to address other hazardous substances (*e.g.,* the costs to pump and treat groundwater; to dig and haul contaminated soil; or to provide alternative drinking water). Therefore, EPA can use historic response cost information to reasonably assess PFOA and PFOS response costs. EPA acknowledges, however, that there remains uncertainty concerning the location and number of sites that will be identified as needing remediation and the extent of contamination at those sites. There is also uncertainty regarding the potential incremental increase in cost (if any) of addressing PFOA or PFOS at a site along with other COCs present.[43]

EPA concluded that a ''totality of the circumstances'' analysis is a useful benchmark for assessing whether action is warranted under a unique statute like CERCLA. Unlike other environmental statutes which are premised on ''command and control'' regulation, CERCLA is a remedial statute. It does not set prospective limits on the amount of permissible contamination. Instead, CERCLA imposes financial liability on those responsible for existing contamination that presents unacceptable risk to public health and the environment. In many instances (*e.g.,* at NPL sites) cost considerations are evaluated on a site-specific basis. A totality of the circumstances analysis best reflects the advantages and disadvantages of designation and allows for a more holistic assessment of designation.

The totality of the circumstances analysis is provided below. Section VI.A discusses the numerous advantages of designation. Designation allows EPA to deploy the full suite of CERCLA tools to identify, characterize, and cleanup the most contaminated sites expeditiously. It also allows EPA to hold responsible those parties that have contributed to significant contamination so that they bear the costs of cleaning it up. This, in turn, makes more resources available, allowing for additional and/or earlier cleanups relative to what could occur absent designation. These additional, earlier cleanups will protect vulnerable populations and communities living near contaminated sites. Further, these cleanups will have meaningful health benefits similar to other CERCLA actions by reducing a broad range of potential adverse human health effects. Thus, cleaning up PFOA and PFOS contamination that is posing unacceptable risk to human health, or the environment will improve quality of life and reduce health care expenditures for the communities living in and around PFOA and PFOS contaminated sites.

Section VI.B evaluates the disadvantages of designation such as direct costs of the rule, the potential for the rule to create hardship for parties that did not significantly contribute to contamination, and the potential for uncertainty for PRPs. EPA estimates that direct costs, particularly release notification costs, are fairly minimal. EPA recognizes that some parties that do not bear primary responsibility for contamination may be sued and face uncertain litigation costs. EPA believes that CERCLA's liability limitations, coupled with EPA enforcement discretion policies, should operate to minimize hardship for parties that did not significantly contribute to contamination. EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades (with respect to the more than 800 existing hazardous substances) to resolve who should pay for the cleanup and how much.

In Section VI.C, EPA explains the results of the totality of the circumstances analysis to demonstrate that potential costs and disadvantages are not unreasonable when weighed against the numerous advantages of designation.

A. Advantages of Designation

EPA examined the advantages of designation, including its positive impacts on public health, the Superfund program, local economies and ecosystems, and the importance of shifting response costs to parties responsible for significant contamination. Unlike other environmental statutes which are premised on ''command and control'' regulation, CERCLA is a remedial statute. It does not set prospective limits on the amount of permissible contamination. Instead, CERCLA imposes financial liability on those responsible for existing contamination that presents unacceptable risk to public health and the environment. As a consequence, benefits of the designation flow from CERCLA's liability framework—which leads to more cleanups of existing contaminated sites—rather than the prospective regulation of releases at regulated sources.

Designating PFOA and PFOS as CERCLA hazardous substances eliminates barriers to timely cleanup of contaminated sites, enables EPA to shift responsibility for cleaning up certain sites from the Fund to PRPs, and allows EPA to compel PRPs to address additional contaminated sites. Ensuring the timely cleanup of sites, and that the parties responsible for significant contamination bear the costs of cleaning it up, are the primary objectives of CERCLA. EPA gave significant weight to these considerations because, absent designation, the cleanup of PFOA and PFOS contamination would be significantly hampered. PFOA and PFOS contamination is widespread, and EPA's current authority is limited.

Earlier and more timely responses at contaminated sites will better address the urgent public health issue of PFOA and PFOS contamination. As discussed above in Section V, the latest science is clear: human exposure to PFOA and PFOS is linked to a broad range of adverse health effects. EPA gave significant weight to its finding that both PFOA and PFOS may present substantial danger. The potential for harm to public health is unabated if PFOA and PFOS remain in the environment, and designation is necessary to facilitate swift action. EPA also gave significant weight to the substantial health benefits—realized by communities nationwide—that are expected to result from designation. Earlier, expeditious response to PFOA

[43] Designation does not require any specific response actions or confer liability. Whether response costs will be incurred is wholly dependent on site-specific discretionary decisions. Before taking any action, EPA evaluates the level of risk posed by any given release.

and PFOS releases will reduce exposure to PFOA and PFOS across the country and will minimize the likelihood of adverse health effects, particularly for sensitive groups such as pregnant woman and children. As discussed *supra* in Section V, PFOA and PFOS exposure is linked to serious health conditions, including cancer and cardiovascular disease. Reducing PFOA and PFOS exposures can improve community health while potentially saving Americans billions of dollars in health care and other expenses. PFOA exposure alone has been estimated to have caused billions of dollars of health care and other economic costs (*Malits et al., 2018*). EPA also quantified certain potential health benefits associated with reducing PFOA and PFOS exposure in private drinking water wells. Designation allows for earlier, and additional, CERCLA response activities to address areas with high levels of PFOA and PFOS contamination, which translates to lower risk of adverse health effects for the most exposed communities. Ensuring that EPA can utilize CERCLA to the fullest extent is critical to address this serious public health issue.

1. Designation Enables Earlier, Broader, and More Effective Cleanups of Contaminated Sites

Designation of PFOA and PFOS as hazardous substances is critical to EPA's ability to address the public health threats posed by PFOA and PFOS in the environment. CERCLA imposes notification requirements and potential liability on those that release hazardous substances and makes available authorities that promote timely cleanup of hazardous substances. This includes release notification under CERCLA section 103, response authority under CERCLA section 104, enforcement authority under CERCLA section 106, and cost recovery under CERCLA section 107. Thus, designation allows EPA to employ a broader suite of CERCLA authorities to address contamination, which in turn allows EPA to address more sites, enables earlier and more expeditious responses to PFOA and PFOS releases, and makes available additional resources allowing for cleanup of other COCs at NPL sites. It also provides EPA with authority to pursue those responsible for the most significant contamination so that they bear the financial responsibility for cleaning it up.

a. Designation Opens Up CERCLA's Notification, Response, Enforcement and Cost Recovery Authorities, Which Allows EPA to More Timely Address Contaminated Sites

This action will make PFOA and PFOS subject to CERCLA's notification, response, enforcement, and cost recovery authorities. This is because those authorities either do not apply, or are limited, with respect to pollutants or contaminants (which PFOA and PFOS are currently).

A direct consequence of designating PFOA and PFOS as hazardous substances is that, once designated, entities that release PFOA and PFOS at or above the reportable quantity must provide notification of the release. The requirements include notification to the National Response Center for releases that meet or exceed the reportable quantity, CERCLA section 103; newspaper notice to parties potentially injured by a release, CERCLA section 111(g); and State, local, and Tribal notice, as appropriate, for reportable releases, EPCRA section 304. These notifications allow EPA to assess whether CERCLA response actions are necessary to mitigate risks to public health and the environment and to respond promptly where response actions are necessary. Swift action to address harmful releases can prevent further migration of PFOA and PFOS from the source of the release and reduce the need for more expensive, more expansive cleanup in the future.

Designation also allows EPA to streamline the Federal government's response authority under CERCLA section 104 to address releases or threatened releases using removal or remedial authority. Absent designation, EPA (and other Federal agencies) can only address PFOA and PFOS as pollutants or contaminants. This means that, for each individual response, EPA (or another agency) needs to find that a release, or threat of release, ''may present an imminent and substantial danger to the public health or welfare.'' 42 U.S.C. 9604(a)(1). After designation, agencies will be able to respond to a release or threatened release without first making this determination, allowing for action sooner.

Designation also makes CERCLA's enforcement and cost recovery authorities available for PFOA and PFOS. In the absence of designation, CERCLA authority to compel PRPs to conduct or pay for response work does not extend to ''pollutants or contaminants'' and CERCLA does not provide cost recovery for actions taken solely in response to releases or threats of releases of ''pollutants or contaminants.'' Having access to these authorities will allow EPA to hold PRPs responsible for addressing PFOA/PFOS contamination, which can lead to the timely cleanup of more contaminated sites.

Designation will allow EPA to take enforcement actions against PRPs under CERCLA section 106(a) when there may be an imminent and substantial endangerment from an actual or threatened release of PFOA or PFOS. EPA will be able to use CERCLA section 106(a) to compel PRPs to take immediate action to start the time-consuming process of investigating, scoping, and cleaning up PFOA and PFOS releases. This authority also helps to ensure that PRPs are financially accountable for releases of PFOA and PFOS by enabling EPA to compel PRPs to undertake response action. This, in turn, enables earlier and more EPA response work by diversifying EPA's options. Enforcement actions are also complementary to Fund-financed response activities (''*Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes,*'' *1982*). EPA aims, whenever possible, to seek cleanup by responsible parties prior to recourse to either the Fund or litigation. This allows EPA to preserve the valuable resources of the Fund to address as many priorities as possible.

Enforcement authority contributes to timely response actions at the most contaminated sites. Because PRPs, rather than EPA, are best positioned to know the location and extent of potential contamination at and from their facilities, PRP-led cleanups can be more efficient. PRP-led cleanups can also be faster because EPA need not secure access orders with PRPs if the PRP is conducting the response actions. Also, EPA generally takes enforcement actions to address sites that pose the highest relative risks; therefore, making enforcement authority available supports EPA's ability to target and prioritize existing sites where PFOA and PFOS releases pose substantial risk to public health and the environment.

Additionally, designation will allow EPA to use CERCLA section 107 to recover costs expended by EPA to clean up PFOA and PFOS contamination. CERCLA section 107 provides that liable parties are responsible for the costs associated with responding to hazardous substances. Liable parties under CERCLA include: (1) Current owners and operators of facilities, (2) past owners and facility operators in place at the time of hazardous substance

disposal, (3) any person who ''arranged for disposal'' of that facility's hazardous substances, and (4) any person that accepts hazardous substances for ''transport to disposal or treatment facilities.'' (CERCLA section 107(a)). If a person is liable for a release of hazardous substances, that person may be responsible to pay for response costs, natural resource damages, and assessment costs, and costs pertaining to certain health assessment or health effects studies. CERCLA section 107(a)(4)(A)–(D).

b. The Availability of CERCLA Enforcement and Cost Recovery Authority Ensures That Polluters Are Financially Responsible, Which Is Consistent With CERCLA

This action will allow EPA to hold polluters responsible for addressing significant contamination. After designation, EPA will have authority under CERCLA section 106 to compel PRPs to take response actions at their facilities. This may allow EPA to reach more sites more quickly. After designation, EPA can also rely on authority under CERCLA section 107 to recover costs expended by EPA to clean up PFOA and PFOS contamination.

The availability of CERCLA enforcement authority to address PFOA and PFOS releases aligns with the Polluter Pays principle, a central objective of CERCLA, and is an important advantage of the rule. CERCLA is specifically designed to hold responsible those parties that contributed to dangers to human health and the environment by releasing hazardous chemicals into the environment. *See* H.R. Rep. No. 99–253, pt. 3, at 15 (1985), *as reprinted in* 1978 U.S.C.C.A.N. 3038, 3038 (stating that a goal of CERCLA is ''to hold responsible parties liable'' for cleanup costs); H.R. Rep. No. 96–1016, pt 1, at 1 (1980) (acknowledging that CERCLA establishes ''strict liability to enable the Administrator to pursue rapid recovery of costs . . . and to induce [liable parties] voluntarily to pursue appropriate environmental response actions . . . .''). The ability to require liable parties to pay for cleanup is the cornerstone of ensuring that sites are cleaned up to protect public health from ''one of the most pressing environmental problems.'' *See* H.R. Rep. No. 99–253, pt 1, at 54 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 2835, 2836. In reauthorizing CERCLA, Congress acknowledged that, ''[I]t is clear from the accumulating data on waste sites that EPA will never have adequate monies or manpower to address the problem itself. As a result, an underlying principle . . . is that Congress must facilitate cleanups of hazardous substances by the responsible parties . . . .'' H.R. Rep. No. 99–253 at 55. Consistent with these legislative goals, this rule enables EPA to hold PRPs, particularly those that have contributed significantly to PFOA and PFOS contamination, financially responsible for addressing such contamination. Designation also signals to the market that there is value in the prevention of releases and mitigation of existing releases.

EPA considered the additional costs that PRPs may face and concluded that these potential costs do not outweigh the advantages of designating PFOA and PFOS. Potential costs associated with CERCLA enforcement actions that may occur after designation are difficult to assess. Nonetheless, EPA used historical cost data to assess the potential for additional costs to PRPs associated with response work at non-NPL sites that may result from enforcement actions, *see Chapter 5 of the RIA for more detail.* EPA cannot ascertain with certainty the number of sites that may be subject to a CERCLA enforcement action over the next several years. Depending on the circumstances, EPA may determine that authority provided under a different statute, such as RCRA, SDWA, CWA, or TSCA, may be best suited to address the environmental harm. In addition, the site could be referred to the State for further action rather than EPA; or site activity could be Fund-lead, which may occur when there is no viable PRP or when immediate action is required. Should EPA proceed using CERCLA enforcement, the scope of the enforcement action—including the response activities required and the amount of time it may take to implement them—is also difficult to estimate absent a preliminary assessment of the scope of contamination at a specific site.

Ensuring that the PRPs responsible for significant contamination bear the costs of cleanup is one of the express purposes of CERCLA and can only be realized through designation. This is an important advantage of designation. Bringing PFOA and PFOS into CERCLA's liability framework is a critical and essential advantage of designation, considering that PFOA and PFOS are prevalent in the environment, threaten communities across the country, and PRPs are best situated to address releases from their facilities. And while it cannot be determined with specificity where or when enforcement and response actions will occur, EPA attempted to estimate anticipated expenditures to the best of its ability. Considering all of this together, EPA concluded that designation achieves a principal objective of CERCLA—the polluter pays. The payment of these costs by those responsible for significant contamination represents an improvement in social welfare as a result of the rule.

c. EPA Expects Designation Will Increase Emergency Response and Removal Actions for PFOA/PFOS

EPA expects that designation will result in more removal actions, including emergency actions, to address PFOA and PFOS releases, which in turn may increase health benefits. These removal actions can be taken by EPA (*i.e.,* Fund-lead actions) or a PRP (*i.e.,* PRP-lead actions).[44] Additional removal actions are expected to occur because EPA prioritizes responses to hazardous substances and in particular those with the greatest threat to human health, and EPA expects an increase in State referrals, each of which are explained in turn.

After designation, EPA expects to take more Fund-lead removal actions for PFOA and PFOS contamination because existing limitations on response authority and cost recovery will no longer apply. EPA's removal program, although not limited to responses to hazardous substance releases, prioritizes responses to hazardous substance releases. This is in part because the removal budget is limited, and the administrative burden for addressing hazardous substances is reduced relative to addressing PFOA/PFOS as pollutants or contaminants. Absent designation, to respond to PFOA or PFOS contamination utilizing CERCLA section 104(a), the statute requires EPA to determine the release or threat of release may pose an imminent and substantial endangerment. The statute also does not allow EPA to cost recover for actions exclusive to pollutants or contaminants. A hazardous substance designation removes those statutory limitations, as EPA need not demonstrate on a case-by-case basis that releases of hazardous substances may pose an ''imminent and substantial endangerment.'' Designation thus enables additional Fund-lead removal actions to address immediate risks.[45]

[44] This section only discusses designation impacts on Fund-lead removals. Designation impacts pertaining to PRP-lead actions, including removal orders, are discussed in section VI.1.b.

[45] When a removal action is appropriate, EPA should take action ''as soon as possible,'' (40 CFR 300.415(b)(3)), and may often choose to take a Fund-lead removal rather than pursing a PRP-lead action through use of CERCLA enforcement authority. Negotiating an enforcement order can be a time-consuming effort, which can in turn delay

EPA can then later recover costs for cleanup of these substances. Recovered costs for each removal action that EPA takes to address sites contaminated with PFOA and/or PFOS are costs that would be shifted from taxpayers to PRPs.

Removal actions to address PFOA and PFOS releases may also increase as a result of State referrals, which often trigger a Fund-lead removal action. States refer sites to EPA when they do not have the capacity, technical expertise, or funding to take action under their own authorities. EPA expects an increase in State referrals to EPA for PFOA and PFOS removal actions because State budgets are limited. And because State budgets are limited, Federal involvement may be the only financially viable path toward responding to PFOA and PFOS releases. EPA is not required to initiate a removal in response to referrals; however, EPA must evaluate the need for removal actions as promptly as possible after receiving the notification and determine the appropriate response. (40 CFR 300.405(f)(1), 300.410(b)). EPA may determine that a Fund-lead removal is the appropriate response or, if not, EPA may continue monitoring the situation should EPA involvement be appropriate at a later point in time.

EPA expects that removal costs for addressing PFOA and PFOS releases will likely be roughly similar to removal costs for other substances. The same response methods that exist for addressing other hazardous substances are available for PFOA and PFOS. As one example, in cases where PFOA and PFOS are contaminating drinking water, removal actions would primarily focus on risk reduction for exposure to contaminated drinking water. Methods of addressing exposure may include granulated activated carbon, ion exchange, connecting customers to the nearest public water system, and/or temporarily providing bottled water. Any contamination left in place would be managed using post-removal site controls [46] or referred to a cleanup program (*e.g.,* State, local, or the Superfund remedial program),[47] dependent on relative risk. EPA expects that Fund-led removal actions to address PFOA and PFOS releases may range from $160,000 to $503,000 per site. *See RIA Chapter 5.* Where PFOA and/or PFOS are the sole driver for initiating a removal action, the cost estimate above represents the estimated cost of the action. Where EPA may be responding to multiple COCs, the cost of addressing PFOA/PFOS would represent an incremental increase to the overall cost of response in addition to those other COCs.

An increase in removal actions for PFOA and PFOS releases is expected to produce meaningful health benefits. Fund-lead removal actions are the fastest way for EPA to respond to the most urgent situations. Removal actions are typically quick responses to immediate threats to eliminate or mitigate a threat to the public. Thus, EPA is able to initiate a removal action more quickly than it can remedial action—actions which often take decades to develop and implement. Through removal actions, EPA can more quickly eliminate or mitigate exposure pathways. For example, if it becomes known to EPA that a resident's drinking water is contaminated with PFOA and PFOS above risk-based levels, EPA can take action to eliminate that exposure pathway by providing alternative drinking water or connecting the resident to an alternative water source. Such actions mitigate the risk of adverse health outcomes associated with chronic and cumulative exposures to PFOA and PFOS. *See Section VI.A.2 of this document, discussion of health benefits.*

d. EPA Expects That Shifting Costs to PRPs To Address PFOA/PFOS Contamination at NPL Sites Will Make Fund Money Available for Other Response Work

Through this action, EPA may compel viable PRPs to clean up PFOA/PFOS contamination. EPA may thus conserve use of the Fund for addressing other COCs or sites where there are no viable PRPs, expanding EPA's ability to provide meaningful benefits for public health and the environment across the country. Absent designation, EPA would continue to spend Fund resources to clean up PFOA and PFOS releases at non-Federal facility NPL sites under EPA's authority to address PFOA and PFOS as ''pollutants or contaminants.'' Prior to this rule, EPA evaluated PFOA and PFOS releases as pollutants and contaminants as part of its process to identify potential NPL sites, in its selection of a remedy, and in evaluation of the remedy. *See supra*—Section II.*E.4, 5.* After designation, EPA will continue to evaluate PFOA and PFOS releases as part of the Superfund process, but now EPA can transfer these costs to PRPs—the entities responsible for the contamination and associated hazards to human health and the environment.[48] Designation or not, EPA has been and will continue to evaluate hazardous substances, pollutants or contaminants, at NPL sites and, if necessary, address releases that present unacceptable risk to human health or the environment. A major difference this designation makes for NPL sites is who bears responsibility.

After designation, parties responsible for significant contamination may bear liability. As discussed in Section VI.A.1.b., the transfer of costs from EPA to PRPs directly advances CERCLA's objective that those that contributed to contamination bear the cost of cleaning it up. While these cost transfers at NPL sites are an important outcome of the designation, the designation itself does not lead to greater response costs at particular NPL sites. Absent designation, EPA would incur these costs, which would be paid by the Superfund. After designation, EPA can transfer these costs to viable PRPs by compelling PRPs to implement response actions at NPL sites or through cost recovery.

The transfer of costs to viable PRPs leads to more total resources available for cleanups. Superfund resources that otherwise would have been used for PFOA and PFOS response actions can now be available for other priorities. Such monies could be made available for additional Superfund response activities at NPL sites to be spent addressing any of the more than 800 hazardous substances, including PFOA and PFOS, as well as other pollutants and contaminants. EPA estimates that this will result in $10.3M to $51.7M (at a 2% discount rate) of Fund resources available each year for NPL response work because of designation. While EPA cannot fully quantify the benefits attributable to funds being available for more response work at NPL sites, EPA

a response. When immediate action is required, EPA will use Fund dollars to initiate a removal and later cost recover.

[46] Post-removal site control (PRSC) means ''those activities that are necessary to sustain the integrity of a Fund-financed removal action following its conclusion.'' (40 CFR 300.5). This may include, for example, replacing water treatment system filters or collecting leachate. Once field actions end, and all EPA resources are demobilized, any additional actions required are PRSCs. PRSCs continue until they are no longer necessary or until such time as a PRP, state or local government, or EPA's remedial program implements a remedy. (40 CFR 300.415(l)).

[47] After EPA takes a removal action, it may be appropriate to refer the site back to the state to maintain PRSCs. The NCP provides that EPA should provide for PRSC, to the extent practicable, before the removal action begins. (40 CFR 300.415(l)). EPA often coordinates with states to obtain a commitment that the state will maintain PRSCs after the removal ends. States may not have funding to undertake the initial removal action, but often are able to budget PRSC costs.

[48] As detailed in the RIA accompanying this rule, these ''cost transfers'' from EPA to the PRP do not result in a net increase in economic costs—rather, they just change ''who pays'' for these cleanup costs.

believes these benefits will be meaningful. More money for NPL response work means that EPA will be able to better address threats to public health and our natural environment from contamination.

Addressing PFOA and PFOS contamination may lead to an incremental increase in the costs associated with addressing NPL sites depending on what other COCs are located at a given site. It is unusual for a remedy to address a sole ''contaminant of concern,'' many of which are hazardous substances. Typically, remedial actions address a number of COCs at once. In some cases, the remedy for other COCs will also address PFOA and PFOS contamination; in other cases, there will need to be additional work to address PFOA and PFOS contamination. For instance, if PFOA and PFOS are not already part of a remedy for the site, adding them to the remedy would then have the potential to incrementally increase the overall cost of the remedy (*e.g.,* by increasing the frequency of GAC replacement). Any costs of cleaning up PFOA and PFOS contamination could then be transferred to PRPs, instead of borne by the Fund. EPA estimates that the incremental cost for addressing PFOA and PFOS releases at NPL sites may range from $10.3 million annually to $51.7 million annually (at a 2% discount rate). *See RIA Chapter 5.* These represent estimated response costs that the Fund would incur absent designation; designation is not expected to result in an overall increase in cost to EPA to address NPL sites. However, the recovery of $10.3M to $51.7M (at a 2% discount rate) of Fund resources each year because of designation will result in EPA continuing to spend that same amount on other Superfund response activities. This represents an increase in resources expended on Superfund response as EPA continues to spend as before and parties responsible for PFOA and PFOS contamination also must spend to address contamination at NPL sites. This represents an indirect incremental cost of the rule.

In sum, EPA concludes that significant advantages of designation are that it will enable earlier, broader, and more effective cleanups of contaminated sites. Designation will provide additional or enhanced notification, response, liability, and enforcement authority under CERCLA. This enhanced authority may allow EPA to address more contaminated sites more quickly. Designation will also ensure that polluters pay for cleaning up contamination that poses unacceptable risks to human health and the environment, which is consistent with CERCLA's objectives. EPA expects to conduct more removal and emergency response actions and that more resources will be available for NPL site response actions. These are significant advantages of the rule because it effectuates the two primary objectives of CERCLA's statutory framework—timely cleanup of contaminated sites and polluter pays—by bringing widespread, persistent chemicals—PFOA and PFOS—under the umbrella of CERCLA's liability framework, which in turn makes more resources available to address this widespread public health threat.

2. Designation Brings Broad Health Benefits

EPA also weighed the health benefits that may indirectly result from designation. EPA considered quantified and unquantified health benefits associated with reducing exposure to PFOA and PFOS, as well as from additional response work at NPL sites. While it is hard to determine with certainty the nature and scope of future response actions, EPA expects that reducing PFOA and PFOS exposure will reduce the risk of adverse health effects, as detailed below.

a. Qualitative Potential Benefits From Decreased Exposure After Addressing PFOA/PFOS Contamination

EPA weighed the indirect potential health benefits associated with removing PFOA and PFOS from the environment. When exposure pathways are mitigated or eliminated, communities living around contaminated sites would be expected to have lower rates of adverse health effects because they are exposed to less PFOA and PFOS. Historical data, such as NPL sites with soil lead contamination and cleanups, demonstrates improved health outcomes after Superfund cleanups.[49] So here, one advantage from designation is that EPA expects overall reductions of adverse health outcomes for exposed communities to occur sooner, in addition to wholly avoided exposure in some instances. EPA expects that additional response actions to address PFOA/PFOS at non-NPL sites resulting from more removals and enforcement actions will reduce or in some cases eliminate exposure to PFOA and PFOS from contaminated sites, resulting in several categories of non-quantified health benefits realized as avoided adverse health effects. As described in section V.A. of this document, PFOA and PFOS exposure can be associated with the following adverse health outcomes:

- Developmental birth effects such as low infant birth weight, birth length, and head circumference
- cardiovascular effects such as changes in cholesterol and blood pressure
- cancer, including renal cell carcinoma
- changes in liver enzymes
- decreased immune response to vaccination
- endocrine effects, including thyroid disorders
- reproductive effects (for PFOA)
- nervous system effects (for PFOS).

Designation provides a robust mechanism to minimize the potential for these adverse health effects from PFOA and PFOS exposure. To the extent that adverse health effects are reduced or avoided, healthcare expenditures to address these outcomes could be reduced, and worker productivity and overall quality of life would be enhanced due to reduced illness and chronic health conditions.

Given that PFOA and PFOS are often expected to be co-located and/or commingled with other chemicals, cleanup at non-NPL sites because of enforcement actions may simultaneously clean up co-contaminants other than PFOA and PFOS that would otherwise go unaddressed, potentially including other types of PFAS. This may include cleanup of co-contaminants from private drinking water wells as well as the source water used for public water supply (to the extent contamination entered source waters and will be cleaned up as a result of this rule). As a result, addressing these co-contaminants has the potential to result in additional health and ecological benefits.

Despite the array of adverse health and environmental risks associated with exposure to PFOA and PFOS, it is technically challenging to quantitatively estimate adverse effects from exposure that will occur absent the designation of PFOA and PFOS as hazardous substances. Furthermore, it is challenging to quantitatively estimate the benefits that may result from designation. In fact, many important benefits (including those associated with possible immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal outcomes) of cleaning up PFOA and PFOS can only be

[49] *Heather Klemick, Henry Mason, and Karen Sullivan. 2020. ''Superfund Cleanups and Children's Lead Exposure,'' Journal of Environmental Management,* 100. doi: 10.1016/j.jeem.2019.102289. For more information: *https://www.epa.gov/superfund/lead-superfund-sites#sites.*

described in qualitative terms due to the lack of robust data. They cannot be quantified or monetized due to data gaps, and due to uncertainty regarding where and when cleanups will occur. But that does not mean that these benefits are small, insignificant, or nonexistent, particularly to the communities CERCLA exists to protect. Quantifying benefits from cleanup of PFOA and PFOS requires data to characterize the risk and quantify the magnitude of expected (cancer and noncancer) health outcomes. Generally, robust data needed to quantify the magnitude of expected adverse noncancer impacts are unavailable, and full quantification of these benefits is made even more challenging by the overlap of effects from PFOA and PFOS exposure. For these reasons, EPA was able to estimate only a few of the many potential benefits from reduced exposure to PFOA and PFOS. The quantified illustrative benefits of addressing PFOA/PFOS contamination discussed below are in addition to the potential qualitative benefits discussed above. EPA believes that the advantages of this action outweigh the disadvantages even without consideration of quantified benefits. The quantified benefits account for only a portion of the overall benefits from the designation of PFOA and PFOS as hazardous substances. That is, addressing PFOA and PFOS contamination in private drinking water wells also results in additional health benefits for additional health endpoints that cannot be quantified, and addressing PFOA/PFOS contamination more broadly brings health and ecological benefits well beyond private drinking water wells. The quantitative benefits described below, however, make clear the meaningful health benefits achieved from reduced exposure to PFOA and PFOS.

b. Quantifiable Health Benefits of PFOA and PFOS Exposure Reduction

In the RIA supporting this final regulation, EPA performed an illustrative estimate of benefits calculated using monetized health benefits estimates per unit reduction of PFOA and PFOS derived for 2024 National Primary Drinking Water Regulation (*U.S. EPA, 2024a*). The estimated benefits attributable to this rule due to reduced PFOA and PFOS levels in private wells (which are not subject to the PFAS NPDWR) are distinct from those attributable to the PFAS NPDWR from reduced PFOA and PFOS in public and community water systems. A portion of benefits from this rule derive from reduced PFOA and PFOS in private wells used for drinking water that may result from addressing contaminated sites, both in the baseline (at NPL sites) and under this final rule (at non-NPL sites). The benefits estimation methodology and results are discussed here. Quantified benefits in the PFAS NPDWR were assessed as avoided cases of illness and deaths (or morbidity and mortality, respectively) associated with exposure to PFOA and PFOS. The PFAS NPDWR provided a quantitative estimate of birth weight and cardiovascular disease (CVD)—avoided morbidity and mortality associated with reductions in PFOA and PFOS. A quantitative estimate of renal cell carcinoma (RCC)—avoided morbidity and mortality for reductions in PFOA was also developed. EPA was not able to quantify or monetize other health benefits, including those related to other reported health effects including immune, liver, endocrine, metabolic, reproductive, musculoskeletal, as well as certain cancers such as combined hepatocellular adenomas and carcinomas. EPA assesses potential benefits quantitatively if evidence of exposure and health effects is likely, it is possible to link the outcome to risk of a health effect, and there is no overlap in effect with another quantified endpoint in the same outcome group. Particularly, the most consistent epidemiological associations with PFOA and PFOS include decreased immune system response, decreased birthweight, increased serum lipids, and increased liver enzymes (particularly Alanine Transaminase (ALT)). The available evidence indicates effects across immune, developmental, cardiovascular, and hepatic organ systems at the same or approximately the same level of exposure.

i. Quantified Developmental Effects

Research indicates that exposure to PFOA and PFOS is associated with developmental effects, including infant birth weight (*ATSDR, 2021; Negri et al., 2017; U.S. EPA, 2016c, 2016d, 202bg, 2024c; Verner et al., 2015; Waterfield et al., 2020*). The route through which the embryo and fetus are exposed prenatally to PFOA and PFOS is maternal blood serum via the placenta. Most studies of the association between maternal serum PFOA/PFOS and birth weight report negative relationships (*Dzierlenga et al., 2020; Negri et al., 2017; Verner et al., 2015*). EPA quantified and valued changes in birth weight-related risks associated with reductions in exposure to PFOA and PFOS in drinking water.

Low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (*Behrman & Rosenzweig, 2004; Chaikind & Corman, 1991; Colaizy et al., 2016; Institute of Medicine, 2007; Joyce et al., 2012; Klein & Lynch, 2018; Kowlessar et al., 2013; Nicoletti et al., 2018*). Recent literature also linked low birth weight to educational attainment and required remediation to improve students' outcomes, childhood disability, and future earnings (*Chatterji et al., 2014; Dobson et al., 2018; Elder et al., 2020; Hines et al., 2020; Jelenkovic et al., 2018; Temple et al., 2010*).

EPA's analysis focuses on two categories of birth weight impacts that are amenable to monetization associated with incremental changes in birth weight: (1) medical costs associated with changes in infant birth weight and (2) the value of avoiding infant mortality at various birth weights.

ii. Quantified Cardiovascular Effects

Cardiovascular Disease (CVD) is one of the leading causes of premature mortality in the United States (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*). As discussed in Section V.A above, exposure to PFOA and PFOS is associated with increased serum PFOA and PFOS concentrations and potentially elevated levels of total cholesterol and elevated levels of systolic blood pressure (*U.S. EPA, 2024b; U.S. EPA, 2024c*). Changes in total cholesterol and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.*, heart attack), ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience (*D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017*).

iii. Quantified Kidney Cancer Effects

The strongest evidence of an association between PFOA exposure and cancer in human populations is from studies of kidney cancer (*e.g.*, renal cell carcinoma (RCC)). Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of kidney cancer (*ATSDR, 2021; California EPA, 2021; U.S. EPA, 2016d, 2024c, U.S. EPA 2024d*). The C8 Science Panel (2012) characterized the evidence for PFOA effects on kidney cancer as ''probable'' based on two occupational population studies (*Raleigh et al., 2014; Steenland & Woskie, 2012*) and two high-exposure community studies (*Barry et al., 2013; Vieira et al., 2013*). A recent study of the relationship

between PFOA and RCC in U.S. general populations found a statistically significant positive exposure-response association between prediagnostic serum PFOA concentrations and subsequent risk of RCC within a population-based US prospective cohort (*Shearer et al., 2021*). This study also observed associations with RCC for PFOS and PFHxS in models unadjusted for other PFAS. However, after mutual adjustment for these 3 chemicals, only the association with PFOA remained statistically significant. As such, EPA selected RCC as a key outcome when assessing the health impacts of reduced PFOA exposures.

In the PFAS NPDWR, EPA quantified and valued the changes in RCC risk associated with reductions in serum PFOA levels that are in turn associated with reductions in drinking water PFOA concentrations. For more details regarding the quantification of benefits from potential reduced developmental, CVD, and RCC impacts, as well as key limitations and uncertainties in that analysis, *See Chapter 6 of the EA for the 2024 NPDWR Final Rule.* (*U.S. EPA, 2024a*).

2. Estimated Health Benefits of PFOA and PFOS Exposure Reduction

For this final CERCLA rule, the quantitative benefit estimates from reducing the adverse health effects described throughout this rule are characterized as illustrative because, in addition to several uncertainties regarding potential cleanups at these sites, it is not possible to estimate the precise magnitude of potential health-related benefits from reducing PFOA/PFOS at these sites. Chapter 3 of the RIA supporting this final rule describes other limitations of the benefits-estimate transfer approach adopted from the PFAS NPDWR, including the simplifying assumption of combining PFOA and PFOS concentrations into one metric and the assumption that benefits per person are linear per PFOA and PFOS part per trillion (ppt) removed.[50]

For context of baseline benefits associated with addressing PFOA/PFOS at NPL sites, the low-end annualized baseline benefits under the assumption 10% of wells within one mile of NPL sites are impacted with 10 ppt reduction in PFOA/PFOS exposure are $430,000 (2% discount rate). The high-end annualized baseline benefits under the assumption 30% of wells near NPL sites are impacted with 200 ppt reduction in PFOA/PFOS exposure are $25,800,000 (2% discount rate). Exhibit 1 shows the results of the illustrative baseline benefits estimates under the scenarios analyzed. Note that these estimates are associated with potential cost transfers as described in Section VI.A.1.d. above and are expected to occur in the baseline (absence of the designation), therefore they are not a result of designation. However, these and other health benefits are expected to be conferred earlier than without designation because designation as hazardous substances reduce the administrative burden on the Agency and makes available enforcement authorities that allow EPA to address PFOA/PFOS contamination sooner.

Exhibit 1. Estimated Illustrative Range of Baseline Annualized Human Health Benefits as a Result of Addressing PFOA/PFOS Contamination at NPL sites (2022$)

% of wells with PFOA/PFOS detections	**2% Discount Rate Estimates**		
	10 ppt reduction	50 ppt reduction	200 ppt reduction
10% of wells	$430,000	$2,150,000	$8,5900,000
20% of wells	$859,000	$4,300,000	$17,200,000
30% of wells	$1,290,000	$6,440,000	$25,800,000

Notes:
1. Values rounded to three significant digits.
2. Results reflect PFOA/PFOS addressed at final, proposed, deleted, and future NPL sites.
3. Benefits estimated are associated with reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma for populations served by private drinking water wells.

As noted previously, the final rule is likely to result in enforcement actions brought by EPA to address PFOA and PFOS releases at non-NPL sites, which are expected to reduce exposure thereby mitigating or eliminating adverse health effects for nearby communities. Due to uncertainties regarding the level of contamination at affected sites, the level of exposure avoided, populations near these sites of concern, and response actions taken, it is not possible to estimate the precise magnitude of potential health-related benefits from reducing PFOA/PFOS at these sites. Given this uncertainty, EPA presents a range of *illustrative* potential health benefits associated with this

[50] The extent to which PFOA or PFOS or both will be reduced at any given site where EPA may implement CERCLA response action is unknown at this time. While PFOA and PFOS are typically found together, to the extent that any CERCLA response action only reduces PFOS concentrations and not PFOA concentrations, the potential health benefits associated with reducing renal cell carcinoma presented here would be overestimated because RCC is associated with PFOA exposure and not PFOS. Further limitations and potential bias are described in more detail in Section 3.5 of the accompanying RIA.

designation. Consistent with the assessment of baseline benefits at NPL sites presented above, the analysis presented here is limited to benefits related to reductions in PFOA/PFOS concentrations in private wells that lead to a reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma. This analysis focuses on sites where EPA may address PFOA/PFOS contamination at non-NPL sites using enforcement authorities made available by designation. These sites may include those that are owned/operated by plastics material and resin manufacturing firms identified as having produced PFOS/PFOA,[51] and sites owned/operated by companies reporting PFOS/PFOA releases (including PFOA/PFOS salts) to EPA's TRI.[52] [53]

Under the low-end assumptions, estimated annualized benefits range from as low as $8,990 to as high as $539,000. These low-end values reflect an assumption that clean up actions are completed in year 19 for each group of sites analyzed. The corresponding range based on the high-end assumptions is $13,000 to $779,000. These high-end values reflect the assumption that response actions are completed in year 1 for each group of sites. Exhibit 2 below shows the results of the illustrative range of benefits estimates under the low-end and high-end scenarios analyzed. For more information about this analysis, *see Section 5.2.2 of the RIA.*

Exhibit 2. Estimated Illustrative Range of Annualized Human Health Benefits as a Result of Addressing PFOA/PFOS Contamination at non-NPL Sites (2022$)

% of wells with PFOA/PFOS detections	Low-End Estimates			High-End Estimates		
	10 ppt reduction	50 ppt reduction	200 ppt reduction	10 ppt reduction	50 ppt reduction	200 ppt reduction
10% of wells	$8,990	$44,900	$180,000	$13,000	$64,900	$260,000
20% of wells	$18,000	$89,900	$360,000	$26,000	$130,000	$519,000
30% of wells	$27,000	$135,000	$539,000	$39,000	$195,000	$779,000

Notes:
1. Values rounded to three significant digits and reflect a 2% discount rate.
2. Results reflect PFOA/PFOS addressed at certain sites where EPA may use enforcement authorities.
3. Benefits estimated are associated with reduced incidence of developmental effects, cardiovascular effects, and renal cell carcinoma for populations served by private drinking water wells.
4. Benefits realized over a period of 77 years.

c. Cost Estimates of Burden of PFAS-Related Disease

EPA also considered the potential for designation to contribute to reduction in the burden of PFAS-related disease by looking at published studies related to PFAS disease burden. Expanding upon the exposure-response literature for PFAS, a recent study published by *Obsekov et al.* (*2023*) estimated a total United States disease burden of $5.52 billion related to PFOA and PFOS in the U.S. in 2018. Based on PFAS exposure data from the NHANES, the study stratified the population into percentile groups according to PFAS concentrations. The incidence of five adverse health effects was then estimated for each group based on exposure-response relationships from the literature. These health effects include: (1) Low birth weight, (2) Childhood obesity, (3) Kidney cancer, (4) Testicular cancer, and (5) Hypothyroidism in women. These health effects were chosen based on the existence of statistically significant associations for each effect derived from published meta-analyses of epidemiological studies. To value the economic costs associated with these health effects, the study relies on a combination of cost-of-illness data (*e.g.,* the costs of hospitalization), human capital-based metrics (*e.g.,* reduction in lifetime income associated with lost IQ points related to low birth weight), and the value of disability-adjusted life years (related to kidney cancer). The study also includes a sensitivity analysis that expands the scope of health effects examined to include health conditions for which relationships with PFAS had been identified in the literature but had not been meta-analyzed. These additional health effects include adult obesity, type 2 diabetes in females, gestational diabetes due to exposure during pregnancy, endometriosis, polycystic ovarian syndrome, couple infertility, female breast cancer, and pneumonia. With these health effects added, the sensitivity analysis in *Obsekov et al.* (*2023*) estimates a PFOS-

[51] Data acquired from: Environmental Protection Agency, ''Enforcement and Compliance History Online (ECHO).'' Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this RIA uses proxy sites identified using sites owned/operated by companies that participated in EPA's PFOA Stewardship Program, under the assumption that the likelihood of PFOA/PFOS contamination is potentially high at these sites.

[52] Environmental Protection Agency, ''Toxics Release Inventory (TRI) Program, 2022 TRI Preliminary Dataset: Basic Data Files,'' July 2023. Accessed at: *https://www.epa.gov/toxics-release-inventory-tri-program/2022-tri-preliminary-dataset-basic-data-files.*

[53] TRI reporting is not currently required for isomers of PFOA and PFOS.

and PFOA-related disease burden of $62.6 billion in 2018. However, the authors recognize ''that some studies for each of the included outcomes might have reported null findings, [and that] the lower bound of economic cost added for this group of outcomes is zero.'' (*Id.*)

e. Environmental Justice (EJ) Analysis

EPA believes that the human health and environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. The demographic analysis of plastics manufacturers, facilities reporting to the Toxic Release Inventory (TRI), and U.S. airports found that people of color and low-income populations are disproportionately represented (except near small/medium airports). In particular, these sites have higher rates of Black, Asian, and Hispanic people surrounding them relative to the national average. This finding holds whether focusing on all such populations within one or three miles of these sites or only such populations served by private wells.

Consequently, EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. To the extent that the final rule leads to additional response actions to mitigate or eliminate exposure to PFOA/PFOS, or to actions that mitigate exposure earlier, health risks for populations living near sites where releases occur may decline. Based on the detailed analysis found in *Section 6.3 of the RIA,* the proportion of the population near these sites identified potential communities with EJ concerns, or (in some cases) people living in structures with a higher probability of containing lead paint (built before 1960) exceeds the national average. Thus, EPA expects that the final rule will at least partially mitigate the existing burden of PFOS/PFOA exposure that falls disproportionately on communities with EJ concerns.

As further context for EJ effects potentially associated with the final rule, published literature concludes that communities with potential EJ concerns, and other socio-economic burdens, have a higher likelihood of exposure to PFAS, including PFOA/PFOS. For instance, reported data from Northeastern University's Social Science Environmental Health Institute published in 2019 show that people of color and low-income populations are disproportionately exposed to PFAS as nearly 39,000 more low-income households (15% more than the expected based on U.S. census data) and approximately 295,000 more people of color (22% more than expected) live within five miles of a site contaminated with PFAS (*PFAS Project Lab, 2019*). In addition, information on the broader links between PFAS exposure and communities with EJ concerns continues to emerge. An August 2021 Natural Resources Defense Council (NRDC) report examined exposure to PFAS in drinking water in California and found that at least 69 percent of State-identified disadvantaged communities have PFAS contamination in their public water systems, and a number of these communities have levels of PFAS contamination that are higher than the State average PFAS concentrations. In their report, NRDC examined the relationship between the PFAS results and California's CalEnviroScreen 3.0 (CES) scores, which measure the environmental burden at the census-tract level. CES identifies communities that are disproportionately burdened by and vulnerable to multiple sources of pollution. The top 25 percent most impacted communities are identified as ''disadvantaged communities'' for the purpose of allocating funds from the State's cap-and-trade climate program (Senate Bill 535). By examining the overlap of CES scores and PFAS results at the census level, NRDC identified census tracts that may be the most vulnerable to PFAS contaminated drinking water. (*Lee, Susan, Avinash Kar, and Dr. Anna Reade, Dirty Water: Toxic ''Forever'' PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities.* Natural Resources Defense Council, New York. 2021). Therefore, this final rulemaking may improve conditions for exposed populations and communities, including communities with EJ concerns that may have greater PFAS exposure than the general population. Designation of PFOA and PFOS as hazardous substances would allow EPA to address more sites and to implement response actions earlier in time at sites contaminated with PFOA/PFOS, including those near exposed populations and communities, than the Agency could otherwise address in the absence of designation.

f. Summary of Potential Health Benefits Resulting From the Designation

EPA estimates that a portion of potential health benefits associated with reduced exposure resulting from addressing PFOA and PFOS contamination in private drinking water around non-NPL sites that may result from EPA exercising enforcement authorities range from $8,900 to $779,000 (2% discount rate) per year, depending on the percentage of private wells impacted, the reduced level of PFOA/PFOS exposure at each well, and when the cleanup is expected to occur. Note that additional health benefits could also arise through other routes of exposure and for other health effects and non-health effects related to PFOA and PFOS that did not have adequate information for monetization in the PFAS NPDWR, which was used to develop estimates of potential indirect benefits of this designation. Remediation of PFOA and PFOS contaminated sites under CERCLA, including sites with contaminated sediment in water bodies, may reduce the transport of these substances to waters that can be sources of water to public water systems (PWS). There are potential health benefits to customers of public PWSs if source waters are cleaned up to levels below the PFAS NPDWR MCLs[54] or are cleaned up before the PWSs take action to comply with the PFAS NPDWR; EPA cannot quantify these potential benefits.

EPA expects that health benefits that would accrue absent this designation through addressing PFOA and PFOS as pollutants or contaminants under CERCLA, and the additional health benefits due to a potential increase in enforcement actions and removal actions, will be realized sooner rather than later because of this designation. Low-end annualized estimated baseline benefits associated with addressing PFOA/PFOS as pollutants or contaminants at NPL sites under the assumption 10% of wells near NPL sites are impacted with 10 ppt reduction in PFOA/PFOS exposure are $430,000 (2% discount rate). The high-end annualized baseline benefits under the assumption that 30% of wells near NPL sites are impacted with 200 ppt reduction in PFOA/PFOS exposure are $25,800,000 (2% discount rate). Designation is expected to result in earlier response actions because the rule will make EPA aware of PFOA/PFOS contamination earlier than in the baseline (at both NPL and non-NPL sites). As described previously, designation allows EPA access to enforcement authorities to investigate potential releases and compel PRPs to address releases and requires notification of releases above the RQ. These factors may allow for

[54] MCL—Once the MCLG is determined, EPA sets an enforceable standard. In most cases, the standard is a maximum contaminant level (MCL). The MCL is the maximum level allowed of a contaminant in water which is delivered to any user of a public water system. (*https://www.epa.gov/sdwa/how-epa-regulates-drinking-water-contaminants.*)

timelier cleanup relative to a world without the rule. EPA also expects that industry may improve best practices and handling procedures to prevent or mitigate releases of PFOA and PFOS that, in turn, could result in less expensive cleanups over the long run.

3. Property Reuse and Social, Economic, and Ecological Benefits That May Result From Designation

Superfund cleanups have a proven track record of contributing to social, economic, and ecological benefits. EPA expects similar benefits to accrue as a result of more PFOA and PFOS cleanups that will occur after designation. As a first step, EPA considered studies that evaluated property value trends for communities living around contaminated sites that were cleaned up. Some studies evaluated communities surrounding Superfund sites and other RCRA facilities. RCRA studies examining the effects of remediating hazardous waste sites are also illustrative of how cleanups can improve property values for nearby communities. Thus, EPA considered both sets of studies in evaluating how designation may contribute to increased property values.

Many studies demonstrate that cleaning up contaminated sites can positively improve property values. Residential property values within 3 miles (4.8 kilometers) of Superfund sites may increase as much as 18.7 to 24.4 percent when sites are cleaned up and deleted from the NPL. Research specific to RCRA cleanups also suggest that property values may improve from cleanup, perhaps as much as five percent (*Taylor et al., 2016*). Improved property values also have social equity and environmental justice benefits. Communities near Superfund sites tend to be more disadvantaged than those living farther from the sites, and so increased housing values may provide the most benefit to the poorest segments of the population as opposed to other population groups. Cleanup may help correct sociodemographic disparities in access to a clean and safe environment.

EPA also considered the potential for designation to support returning property to beneficial use. Superfund cleanups also make property usable for various purposes. Many Superfund sites—often vacant and underused areas—can become valuable local assets after cleanup. Many once-blighted properties across the country are now in use for a wide range of purposes, including shopping centers, offices, public parks, recreational fields, wildlife habitat, neighborhoods, and renewable energy facilities. Cleanups can also deter blight, vandalism and trespassing. *https://www.epa.gov/superfund/superfund-program-protecting-healthy-communities-advancing-environmental-protection#community_anchor.*

Sites in reuse and continued use can revitalize a local economy with economic benefits such as jobs, new businesses, tax revenues, and local spending. As of FY 2022, more than 1,040 Federal and non-federal [55] NPL sites support new and ongoing uses. EPA has collected data on more than 10,250 businesses at 671 non-Federal NPL sites. In FY 2022, these businesses generated $74.1 billion in sales and employed more than 236,802 people who earned a combined income of more than $18.6 billion. Over the last 12 years (2011–2022), these businesses' ongoing operations have generated over $589 billion (inflation adjusted) in sales. *https://www.epa.gov/superfund/superfund-remedial-annual-accomplishments-metrics#redevelopment.*

EPA considered the potential for designation to contribute to ecological benefits, such as ecological reuse and ecosystem services. Superfund cleanups can reduce or reverse damage to ecosystems and generate ecological or recreational reuse activities. These improvements can contribute to a thriving local community and spark local investment, which can improve local well-being, quality of life, employment rates, property values, and tax revenue generation. While the exact monetary value of ecosystem services and ecological reuse can be challenging to measure, historical evidence shows they provide meaningful benefits to communities. Ecosystem services support all facets of human systems, providing trillions of dollars in amenities and important natural capital. New or restored ecosystems as a result of Superfund actions can generate important economic benefits. See EPA document on the Agency's website, *Ecosystems at Superfund Sites, Reuse and the Benefit to Community. https://semspub.epa.gov/work/HQ/100003256.pdf.* Cleanups can produce a range of ecosystem services—timber, purification of surface water and recreation opportunities, habitat to use for new hives to support pollinators, and enhance flora and fauna, among others. It can lead to ecological and recreational reuse activities, which include waterbodies, wildlife sanctuaries, nature preserves, wetlands, pollinator habitats, forests, grasslands, beaches, and forests. Recreational reuse can also include the installation of athletic fields, parks, playgrounds, and trails. Now there are nearly 2,000 ecological and recreational reuse activities at about 460 Superfund sites. EPA expects that PFOA and PFOS cleanups can contribute to similar benefits.

In summary, past experience shows that cleaning up Superfund sites can restore ecosystems, allow for beneficial reuses of the sites (*e.g.,* shopping centers, parks, ecological or wildlife sanctuaries) spurring and revitalizing local community economies, increase property values and tax revenues, create jobs, and improve the quality of life and well-being those living on or near sites. *EPA expects similar benefits to accrue from designation.* EPA expects, as a result of designation, that these economic, social, and ecological benefits will also be realized sooner rather than later. Designation will bring PFOA/PFOS entirely into the Superfund program, including investigation, cleanup, enforcement, and liability.

4. Some Facilities May Adopt or Improve Best Practices To Prevent Future Releases of PFOA and PFOS

To the extent they have not done so already, some facilities that use or have legacy stocks of PFOA and PFOS and products that contain these substances may adopt best practices to prevent any future releases and adopt best practices to manage waste that contains these substances and products. Other facilities, such as landfills, firefighting training facilities, metal plating facilities and textile coating operations—may improve their best practices as a result of designation.

Congress considered this benefit when enacting CERCLA: ''Expenditures to prevent a threatened release, discharge, or disposal may be necessary if damages are to be avoided while also providing considerable savings when compared to the costs of removal after a release, discharge or disposal has occurred.'' S. Rep. No. 96–848, at 51 (1980). Better waste management practices could result in fewer releases and in cost-savings.

B. Potential Disadvantages of Designation

EPA assessed potential disadvantages of designation and weighed those against the advantages. The disadvantages include direct costs, indirect costs associated with potential response activities, and the potential for uncertainty. For indirect costs, at the outset, EPA acknowledges that there is

[55] While all NPL sites are overseen by the federal government, the term non-federal NPL sites is used in this context to refer to sites that are not federally owned.

uncertainty associated with both quantified and unquantified potential costs; including response costs, costs that may arise from a judgment of liability, and litigation costs. The magnitude of costs arising from liability and litigation are linked to response costs, and future response costs that may arise after designation are uncertain. Additionally, CERCLA is a discretionary statute and decisions are made on a site-by-site basis. Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate, discretionary actions and meeting certain statutory and regulatory requirements, as described below. In addition, future discretionary decisions about cleanup and response are difficult to quantify due to numerous uncertainties such as: (1) how many sites have PFOA or PFOS contamination at a level that warrants a cleanup action; (2) the extent and type of PFOA and PFOS contamination at/near sites; (3) the extent and type of other contamination at/near sites; (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and (5) the cleanup level required for these substances at each individual site. Designation alone does not require EPA to take response actions, does not require any response action by a private party, and does not determine liability. As such, none of the indirect costs associated with response, liability, or litigation that EPA estimates are costs that are certain to be incurred after designation.

EPA also considered potential liability, including the risk of a judgment of liability and associated litigation costs, that may arise after designation. EPA was unable to quantify these costs. Liability and litigation are directly tied to response actions taken for any given release, and as explained, future response costs are uncertain. EPA assessed data that may inform potential liability and litigation costs, but ultimately determined that such data was insufficient to quantify these costs given the number of variables that inform potential liability and litigation. Nonetheless, EPA gave careful consideration to CERCLA's liability scheme, and the impact designation may have on CERCLA liability. EPA concludes that designation will not change CERCLA's liability framework. Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. This conclusion is supported by an analysis of CERCLA's statutory limitations, EPA's existing enforcement discretion policies, CERCLA settlement authorities, and CERCLA's parameters for cost recovery and contribution actions.

The disadvantages from designation are discussed in turn.

1. Direct Costs

EPA evaluated direct costs that may result from designation and determined that there are three categories of direct effects that result from designation: notification and reporting requirements pursuant to CERCLA section 103(a) and section 111(g), as well as EPCRA section 304(a); Federal property sale and transfer requirements pursuant to CERCLA section 120(h); and designation of these substances as hazardous materials under the HMTA, see CERCLA section 306(a). EPA analyzed direct costs that may arise from those requirements, as explained below.

Direct costs that may result from designation are limited to costs associated with notification requirements and are expected to not exceed $1,630,000 in annualized costs. EPA estimated potential notification costs for facilities that must comply with CERCLA section 103(a), CERCLA section 111(g), and EPCRA section 304. Reporting and notification requirements are only triggered in the event of a PFOA or PFOS release that meet or exceed the reportable quantity. Per release, the estimated cost for a facility is expected to be no more than $2,658. This is a minimal financial burden compared to the benefit of having more immediate information about significant releases of PFOA and PFOS. Reporting will result in increased transparency about releases of PFOA and PFOS, which will inform our understanding of these substances in the environment and allow EPA to respond as necessary. In addition, State, Tribal and local officials will receive immediate notification of these releases so these entities can take actions to protect the community where release occurs.

EPA also considered direct costs that may be associated with DOT regulations under CERCLA section 306 and Federal property sales and transfers under CERCLA section 120(h). EPA has not estimated the cost to DOT to implement this requirement but expects it to be minimal; additionally, EPA estimates the subsequent indirect incremental costs to shippers as zero or negligible. The number and magnitude of future Federal property sales and transfers involving property contaminated with PFOA and/or PFOS is highly uncertain and cannot be known at this time. Due to this uncertainty, EPA does not attempt to quantify these costs.

2. Potential Hardship for Parties That Did Not Contribute Significantly to Contamination

EPA also considered how designation may impact CERCLA liability for PRPs. As discussed in Section VI.A, as an advantage of designation, it ensures that parties that contributed to releases of PFOA and PFOS are responsible for response costs necessary to cleanup those releases. For PRPs that have significantly contributed to PFOA and PFOS contamination, imposing liability is appropriate and necessary to address this public health threat. However, EPA also gave serious consideration to potential liability for parties that have not played a significant role in contamination, such as parties that did not generate PFOA- or PFOS-contaminated waste.

For those parties that have not played a significant role in contamination, EPA examined the role of CERCLA's liability limitations and protections in safeguarding against liability. EPA also considered how EPA's existing CERCLA enforcement discretion and settlement policies may offer protection from litigation in some situations that may arise after designation. EPA also considered the role that CERCLA settlements may play in resolving potential liability and limiting litigation risk. Taken together, EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades to resolve who should pay for the cleanup and how much. EPA expects that those parties that are primarily responsible for contamination will bear the brunt of costs to address PFOA and PFOS releases while parties that are not primarily responsible can rely on statutory protections to limit liability, settlement with EPA to secure contribution protection, and EPA enforcement discretion to provide additional comfort. Indeed, this is how CERCLA has operated for decades with respect to the more than 800 hazardous substances already covered by CERCLA. Below, EPA examines CERCL's liability framework, including CERCLA's limiting provisions, EPA's enforcement discretion policies, and relief available under CERCLA's primary causes of action.

CERCLA includes a number of provisions that may limit liability or the financial impact of liability. These include:

- *De minimis or de micromis parties:* CERCLA provides EPA the ability to settle with parties whose contribution is

minimal in comparison to other parties and provides a statutory exemption to de micromis parties. CERCLA section 107(o).

- *Third-Party Defense:* Parties may have a defense to liability if they can show that the contamination was solely caused by acts or omissions of a third party. CERCLA section 107(b)(3).
- *Residential, small business and non-profit generators of municipal solid waste (MSW) Exemption:* This exemption provides an equitable methodology for resolving CERCLA liability of certain MSW generators and transporters. CERCLA section 107(p).
- *Bona Fide Prospective Purchasers (BFPP):* Parties that meet the threshold criteria and continuing obligations for a BFPP are provided with CERCLA liability protection. CERCLA section 101(40).
- *Innocent Landowners (ILO):* Certain entities that acquire contaminated property with no knowledge of the contamination at the time of purchase may be protected from CERCLA liability. CERCLA section 101(35).
- *Contiguous Property Owners (CPO):* This provision protects parties that are victims of contamination caused by a neighbor's action. CERCLA section 101(q).
- *Permit Shield Defense:* CERCLA liability is limited for certain releases that fall within the federally permitted release provision of CERCLA. CERCLA section 101(10).
- *Normal Application of Fertilizer:* CERCLA provides that the ''normal application of fertilizer'' does not constitute a release and, therefore, does not trigger liability under the statute. CERCLA section 101(22).22).

EPA also considered the Agency's existing CERCLA enforcement policies that may mitigate liability concerns and litigation risks. EPA will continue to follow its ''Enforcement First'' policy, which provides that EPA will aim to compel viable PRPs to conduct and pay for cleanup before resorting to the Fund. EPA's existing enforcement discretion policies generally reflect EPA's interest in pursuing major PRPs over minor PRPs. For example, EPA's ''Policy Towards Owners of Residential Properties at Superfund Sites'' (*U.S. EPA, 1991*) is designed to relieve residential owners of the fear that they might be subject to an enforcement action involving contaminated property, even though they had not caused the contamination of the property. EPA's ''Final Policy Toward Owners of Property Containing Contaminated Aquifers'' (*U.S. EPA, 1995*) similarly provides assurance to certain property owners that EPA will not take enforcement actions against them when the landowner did not cause, contribute or exacerbate release of the hazardous substances.

CERCLA's limiting provisions and EPA's enforcement policies work together to support equitable outcomes. Residential landowner PRPs provide a helpful example of how these provisions may work together. Residential landowners may avail themselves of statutory protections such as those available to Bona Fide Prospective Purchasers, Contiguous Property Owners, or ''innocent landowners.'' These protections are self-implementing, which means the protections provided under the statute are automatic, and all a landowner must do to be protected is comply with the requirements of the statute. EPA also has policies in place that provide further comfort to residential landowners, such as the residential landowner policy mentioned above.

Existing limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. No additional action is necessary to ensure that those limitations and policies continue to operate as they have for decades. Nonetheless, although unnecessary to justify designating PFOA and PFOS as hazardous substances, EPA intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for CERCLA enforcement in the context of PFOA and PFOS releases.[56] As EPA states in the FY 2024–2027 National Enforcement and Compliance Initiatives (NECI) (*August 17, 2023*) (*Uhlmann, 2023*), the Agency expects to ''focus on implementing EPA's PFAS Strategic Roadmap and holding responsible those who significantly contribute to the release of PFAS into the environment . . . .'' The NECI also clarifies that EPA ''does not intend to pursue entities where equitable factors do not support CERCLA responsibility, such as farmers, water utilities, airports, or local fire departments, much as [EPA] exercises CERCLA enforcement discretion in other areas.'' EPA may exercise enforcement discretion on a site-by-site basis informed by site-specific circumstances.

CERCLA has additional mechanisms that may operate to temper financial responsibility if a party is potentially liable to equitably resolve how much each party should pay for the costs of cleanup. Under CERCLA section 113(f), liable parties that believe they paid more than their fair share of response costs at a site may, in certain circumstances, seek contribution from other liable parties. In resolving contribution claims, courts consider equitable factors. *See infra-Section VI.B.3.* CERCLA settlements can also operate to balance equities. CERCLA settlements include protection from CERCLA contribution claims by other PRPs related to the matters addressed in the settlement, CERCLA section 122(h)(4), which should help limit litigation and associated costs. In addition, EPA settlements with major PRPs may provide contribution protection for non-settling parties. For example, if EPA settles with a PFAS manufacturer, EPA may secure a waiver of rights providing that the PFAS manufacturer cannot pursue contribution against certain non-settling parties to that settlement. The waiver of rights helps provide some protection to parties that EPA does not intend to pursue from both the costs of litigation and the costs of cleanup. Without such a waiver, settling major PRPs could pursue contribution under CERCLA from those parties for a portion of the CERCLA cleanup.

CERCLA has several mechanisms that can operate to mitigate liability concerns and temper CERCLA's liability scheme. EPA expects these mechanisms to continue to operate as they have for decades to ensure that designation does not result in inequitable outcomes. This conclusion is supported by the fact that PFOA and PFOS are similar to other hazardous substances, and CERCLA's liability scheme has functioned in a rational way as to these hazardous substances. Specifically, several designated hazardous substances have a similar fate and transport to PFOA and PFOS and are similarly ubiquitous. *See* 40 CFR 302.4. CERCLA hazardous substances, such as the chlorinated solvents trichloroethene (TCE) and tetrachloroethene (PCE), as well as heavy metals like mercury and arsenic are prevalent in the environment. TCE and PCE, for example have been found at over 800 NPL sites as well other contaminated sites from their use as industrial solvents including TCE's use for degreasing manufactured metal parts and PCE's use for dry cleaning. Heavy metals, like mercury and arsenic, are

[56] To help EPA develop a CERCLA PFAS enforcement discretion and settlement policy, EPA held two public listening sessions to solicit individual public input on CERCLA PFAS enforcement concerns. The input received will be reviewed and considered by EPA in drafting the policy. EPA's CERCLA PFAS enforcement discretion and settlement policy is aimed at addressing stakeholder concerns and reducing uncertainties by clarifying when EPA intends to use its CERCLA enforcement authorities or its CERCLA enforcement discretion.

commonly found in soil and groundwater. Arsenic has been found at over 1100 NPL sites and mercury at over 600 sites. Some municipalities also encounter these substances on a regular basis from industrial wastewater discharges. Property owners may also handle these substances as a result of home renovations or gardening or normal activities. For example, TCE can be found in some cleaners sold for household use, including paint removers, glue, spot and stain removers, carpet spot removers, metal cleaners, and gun cleaners. Mercury is found in fluorescent light bulbs and is also found in some water bodies as a consequence of pollution from industrial and mining wastes, powerplant emissions, and other sources. This mercury contamination in turn affects fish and those that consume these fish (*U.S. EPA, 2023f*). In addition, americium, a radioactive element that is on the hazardous substances list is found in household smoke detectors. Similarly, PFOA and PFOS were historically manufactured on a broad scale, have past and continued releases to the environment (*e.g.,* through legacy disposal, release of precursors, or manufacture as a byproduct), and are detected widely in multiple environmental media, including groundwater, surface water, wild animals, livestock, and plants. Despite the fact that people come into contact with these hazardous substances on a regular basis, CERCLA has continued to operate in a rational way, generally protecting those that have played little to no role in significant environmental contamination from liability.

3. Potential Litigation, Liability, and Uncertainty

EPA considered the potential for litigation costs, such as attorney's fees and costs associated with negotiating settlements, following the designation. EPA was unable to quantify these costs given the number of variables that inform potential litigation. In addition to threshold issues associated with liability considerations described previously, variables that inform litigation may include, among others: whether EPA takes a response action; whether there are viable PRPs; the number of parties involved in the litigation; whether it is cost effective for a party to pursue litigation; and whether litigation results in settlement or goes to trial. There also remains an open question of how many actions are taken pursuant to CERCLA or taken pursuant to a State Superfund law. Whether an action is taken pursuant to CERCLA or State law creates an additional level of uncertainty that makes it difficult for EPA to fully evaluate and quantify the potential litigation costs associated with designation.

CERCLA is, in part, a liability statute and is designed to ensure that those responsible for the contamination pay to clean it up. Some amount of litigation to resolve ''who should pay'' is an expected, and intended, aspect of CERCLA, and this is true in the context of actions to address PFOA and PFOS releases as well as the more than 800 hazardous substances that are already within CERCLA's scope. EPA considered how CERCLA may operate to minimize the risks posed by litigation. EPA evaluated how CERCLA's primary causes of action—cost recovery and contribution—operate to resolve liability. EPA also considered the role that CERCLA settlements may play in minimizing risks posed by litigation. EPA weighed these considerations against CERCLA's objective of ensuring the polluter pays.

EPA determined that CERCLA cost recovery and contribution provide parameters that safeguard against excessive litigation, and furthermore, that CERCLA settlements may further mitigate future litigation. The presence of a hazardous substance does not create liability under CERCLA. Under section 107, there must be a ''release'' or ''threat of release'' of a hazardous substance and the entity must fall within one of the categories of liable parties. CERCLA section 107(a)(1)–(4). In addition, an entity can only recover response costs that are ''consistent with the NCP.'' Section 107(a)(4)(B). Further, a party's potential liability may be limited as a result of contribution or settlement, CERCLA section 113(f). The statute provides that a party that resolves its potential liability with the United States or a State in a judicially approved settlement is entitled contribution protection—the ability to block third-party claims for matters addressed in the settlement.

In addition to CERCLA's limiting provisions, litigation may also be constrained by the relief available. Private party CERCLA cost recovery actions are limited to relief associated with certain costs and damages. Most notably is the relief permitted for response costs, which is limited to costs incurred ''consistent with the NCP.'' The NCP provides a technical and detailed process for implementing response actions and creates benchmarks that may limit actions that have no discernible human health, welfare, or environmental benefit. Parties also may only receive reimbursement for response costs incurred, and so a party would need to have the financial means to conduct a cleanup before obtaining any recovery. Those parameters may operate to limit frivolous lawsuits or excessive litigation.

Courts' assessment of equitable factors in allocating cleanup costs can also serve as an important limitation on liability. In resolving contribution claims, courts typically allocate a particular party's share of costs based on equitable factors. As a result, courts aim to resolve claims in an equitable manner, which generally results in those that contributed significantly to contamination bearing the most liability; those that did not will bear only a small percentage of response costs, if any. The equitable factors that courts generally apply include: the volume and toxicity of the hazardous substances and their wastes contributed to the contamination by each party; the degree of involvement in generating the hazardous substances or wastes released/deposited; the degree of care exercised in handling the hazardous substances; and the degree of cooperation by the parties with government officials in preventing further harm to public health or the environment.[57] These factors are designed to ensure that those who have contributed significantly to contamination bear financial responsibility for cleanup. Given the information before the Agency, including the comments on the proposal, EPA does not believe that designation is going to result in widespread, significant liability consequences for parties that lack meaningful responsibility for the contamination at issue.

Contribution claims are further limited by CERCLA settlements that provide contribution protection, and such settlements may serve to prevent contribution lawsuits against settling parties. A party that resolves its liability through a CERCLA settlement with the United States will not be liable for third-party contribution claims related to the matters addressed in the settlement. This means that PRPs will not be able to pursue the settling parties for

[57] *See, e.g., United States* v. *A&F Materials Co.,* 578 F. Supp. 1249, 1256 (S.D. Ill. 1984) (establishing equitable factors for apportioning financial responsibility (*i.e.,* the ''Gore Factors'')); *see also In re Bell Petroleum Services, Inc.,* 3 F.3d 889, 894 (5th Cir. 1993) (discussing considerations for apportioning liability among contributors); *Waste Mgmt. of Alameda County, Inc.* v. *East Bat Reg'l Park,* 135 F. Supp. 2d 1071, 1089–90 (N.D. Cal. 2001) (in exercising its discretion on allocation, court does not need to limit itself to any particular set of factors, courts may consider factors appropriate to balance the equities in the totality of circumstances).

contribution costs under CERCLA related to the settlement, thus minimizing litigation costs and discouraging third-party litigation. In certain situations, parties may qualify for *de minimis* or *de micromis* settlements under the terms of the Agency's 2002 enforcement discretion/settlement policy. On a case-by-case basis, EPA may enter into limited ''ability to pay'' settlements with parties to resolve CERCLA response costs, where payment could result in undue financial hardship for the PRP. Further, parties may also be asked to perform actions such as in-kind services, including PFAS monitoring activities and implementing institutional controls.

EPA also considered the potential for CERCLA litigation that may arise as the result of ''voluntary'' private-party cleanup or as the result of cleanup conducted or ordered pursuant to a State program. The safeguards and limitations on CERCLA liability discussed in this section are equally applicable in the context of CERCLA litigation arising from voluntary or state-led cleanups. Such litigation is subject to the same paradigms as litigation that arises out of a Federal-led CERCLA action.

EPA acknowledges though that some parties that do not bear primary responsibility for contamination may be sued and face litigation costs as a consequence. These costs cannot be known at this juncture with reasonable certainty. Notwithstanding this, EPA believes that statutory safeguards described above will likely limit this type of litigation or adverse outcomes. Even if litigation costs are incurred by parties that do not bear primary responsibility, EPA does not believe that the potential for such costs will outweigh the substantial advantages of designation discussed above.

C. Results of Totality of the Circumstances Analysis

Taken together, weighing the advantages and disadvantages of the designation alongside EPA's determination that both PFOA and PFOS may present a ''substantial danger,'' EPA concludes that designation of PFOA and PFOS as hazardous substances is warranted. First, the scientific evidence establishes that PFOA and PFOS releases into the environment pose diverse and serious health hazards to exposed populations. The full scope of the hazards from PFOA and PFOS is not yet known, and scientists continue to gain greater understanding of the effects of these human-made chemicals on public health and the environment. Among other things, the current body of scientific and technical literature establishes that PFOA and PFOS exposure are associated with adverse impacts on pregnant women and developing fetuses, such as an increased likelihood of pregnant women getting preeclampsia and hypertension or that babies will be born with a lower birth weight and smaller head circumference. PFOA and PFOS exposure are associated with increased risk for renal cell carcinoma, a type of kidney cancer. Exposure is associated with an increased risk for many other adverse health effects including cardiovascular effects, such as changes to blood pressure and cholesterol, and thyroid disorders, which in turn can impact heart rate, mood, energy level, metabolism, bone health, pregnancy, and many other functions. *[See section V.A.]* PFOA and PFOS exposure are also associated with decrease immune response to vaccinations, in turn leaving vaccinated individuals more vulnerable to harmful disease. These health risks are documented in an extensive body of scientific and technical literature that is continuing to develop as more is learned about the widespread adverse impacts of PFOA and PFOS exposure.

In addition to the serious potential health hazards posed by these substances, available information about the fate and transport of PFOA and PFOS support EPA's conclusions that these substances remain in the environment for many years (*i.e.,* persistence) and that they can move through air, land, and water (*i.e.,* mobility) after release. These chemicals are sometimes referred to as ''forever'' chemicals because of their strong carbon-fluorine bonds in the ''tail group'' that cause PFOA and PFOS to be extremely resistant to degradation through biological degradation and also through chemical degradation (*i.e.,* photooxidation and hydrolysis).

Other information that EPA considered demonstrates that PFOA and PFOS are prevalent and there is a likelihood of exposure to humans and the environment. PFOA and PFOS are prevalent throughout the environment because they are persistent and have been widely used since the 1940s in a wide range of commercial and consumer products. Currently, the public can be exposed to PFOA and PFOS through a variety of sources, including drinking water, food, and environmental media. PFOA and PFOS have been detected in the drinking water of millions of Americans and are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States (*ATSDR, 2021; Cadwallader et al., 2022; U.S. EPA, 2017, 2024a*). The prevalence of PFOA and PFOS is further demonstrated by the fact that these chemicals were detected in the blood of nearly all of the participants in NHANES. This information indicates widespread exposure to PFOA and PFOS in the U.S. population.

Addressing PFOA and PFOS contamination, including cleaning up contaminated soils and water supplies, can reduce PFOA and PFOS exposure to affected communities, and bring substantial benefits. In particular, individuals living near heavily contaminated sites—that is, those sites that are most likely to be targeted for EPA enforcement action, removal action, or designation on the NPL list for more complex cleanup—often include communities with EJ concerns. These communities are at particular risk from adverse health impacts from PFOA and PFOS exposure as well and so are vulnerable to further cumulative harm.

Designation of PFOA and PFOS as hazardous substances under CERCLA section 102(a) will have concrete, on the ground impact, and reduce serious harm. CERCLA's scheme gives EPA authority to cleanup both pollutants and contaminants (which PFOA and PFOS have long been considered) and hazardous substances. But only once a chemical is designated as a hazardous substance, can EPA employ the full suite of CERCLA authorities. These include: the requirement that authorities be notified of certain releases; the authority to compel PRPs to investigate and cleanup contamination where there may be an imminent and substantial endangerment; and the authority to recover response costs where EPA takes Fund-lead actions. These authorities are critical to addressing existing and future PFOA and PFOS contamination and reducing risk of ongoing exposure to these harmful chemicals.

EPA's analysis shows that designation of PFOA and PFOS as hazardous substances will allow EPA to address more sites and to implement response actions earlier in time than it otherwise could in the absence of designation. This is because designation allows EPA to complement Fund-lead actions with PRP-lead actions. Shifting costs to PRPs to address PFOA and PFOS contamination at NPL sites will make Fund money available for cleanup work at Superfund sites. More cleanups promote economic benefits, such as improved property values and making land available for reuse, which can revitalize a local economy with economic benefits such as jobs, new businesses, tax revenues and local

spending. Designation also removes barriers to taking removal actions, which is expected to result in more short-term actions to address immediate risks. Collectively, these actions are expected to have meaningful benefits to human health and the environment, limit further exposure to PFOA and PFOS, and reduce the spread of PFOA and PFOS contamination. Expeditious response to mitigate PFOA and PFOS releases is particularly important given the chemical properties of these substances which make them persistent and mobile in the environment. While the full extent of health, social, economic, and ecological benefits of the designation cannot be quantified, such benefits are expected to be substantial, bringing particular benefit to vulnerable populations.

Designation also serves CERCLA's key purpose of ensuring that those entities that are primarily responsible for contamination bear the economic burden of cleaning it up. Without designation, EPA actions to address PFOA and PFOS are more limited, and response costs may only be paid for through the Fund. After designation, EPA will have authority to compel action by and recover costs from PRPs, which effectively places financial responsibility on those entities responsible for contamination. When EPA is able to transfer NPL site costs addressing PFOA and PFOS contamination, as described previously, it improves societal equity by ensuring that the Polluter Pays for cleanup rather relying exclusively on Fund resources. Further upholding the Polluter Pays principle of CERCLA, designation allows EPA to compel PRPs to address PFOA and PFOS contamination at sites outside of the NPL. This means that additional sites can be addressed, and contamination can be addressed earlier. ''Polluter pays'' is a central objective of CERCLA as a liability statute. Response costs at NPL sites enabled by transfers from EPA to PRPs are estimated to be $10.3 million annually to $51.7 million annually (2% discount rate). Indirect costs associated with response work at non-NPL sites compelled through enforcement actions is estimated to be $327,000 to $18,100,000 annually (2% discount rate). (*See RIA Chapter 5*). EPA recognizes that designation will result in economic costs borne by PRPs. While CERCLA's primary aim is to ensure that PRPs bear cleanup costs, EPA acknowledges that the costs parties expend to clean up PFOA and PFOS is a burden for them. Notwithstanding this, EPA views the cleanup monies spent by PRPs as an advantage of the rule for the reasons stated above. In addition, EPA believes that these cleanup costs will substantially reduce the hazards posed by exposure to PFOA and PFOS, providing significant health benefits (particularly to sensitive populations) that justify the costs.

EPA recognizes that, under CERCLA, a PRP—including those parties that significantly contributed to contamination and those that did not—may be jointly and severally liable to the government for the entire amount of response costs unless it proves that the harm from the release of hazardous substances is divisible. This is true of all listed hazardous substances. EPA's experience over the past four decades administering CERCLA shows that the statute, combined with EPA's existing enforcement discretion policies, ensure that CERCLA will continue to function in a rational manner, with those primarily responsible for pollution bearing the costs of cleanup.

The decision to designate PFOA and PFOS as CERCLA hazardous substances is supported by CERCLA's legislative aims underpinning CERCLA's enactment. CERCLA was enacted to promote the timely cleanup of contaminated sites and to ensure that those responsible for contamination pay to clean it up. H.R. Rep. No. 99–253, pt. 3, at 15 (1985); *Burlington Northern and Santa Fe Railroad Co.* v. *U.S.,* 556 U.S. 599, 602 (2009) (''The Act was designed to promote the 'cleanup of hazardous waste sites' and to ensure that the costs of such cleanup efforts were borne by those responsible for the contamination.''). Designation ensures that CERCLA activities to address PFOA and PFOS contamination conforms to those objectives. Moreover, CERCLA was enacted to address the challenge of community exposure to hazardous chemicals, like PFOA and PFOS, released into the environment.[58] EPA's decision to designate aligns with Congress's vision for CERCLA as an important Federal tool in removing chemicals from the environment that have the potential to pose serious risks to human health and the environment. Indeed, CERCLA designation is necessary to adequately tackle the threat posed by PFOA and PFOS contamination to communities across the country.

CERCLA authority provides EPA with tools to address immediate and long-term needs for mitigating and eliminating PFOA and PFOS exposures that present unreasonable risk. CERCLA's approach to identifying, investigating, and cleaning up contamination is also designed to promote response for the subset of releases that present the most urgent risks. This is evidenced through CERCLA's removal authorities, NPL listing process, the remedial process, and enforcement authority for imminent and substantial endangerments. CERCLA directs Federal agencies to assess risks by considering the population, the hazard potential of hazardous substances, the potential for drinking water contamination, the potential for direct human contact, the potential for destruction of sensitive ecosystems, and the damages to natural resources that may affect the human food chain. Indeed, with those considerations in mind, a small fraction of sites qualifies for the NPL every year.[59] CERCLA also includes safeguards against excessive cleanup costs relative to the effectiveness of a remedy, and those safeguards are reinforced by CERCLA's cost recovery mechanisms. Collectively, these tools ensure that CERCLA prioritizes and targets releases that pose the most risk to human health and the environment; ensures that EPA can respond quickly when necessary and design durable, long-term remedies that ensure protection for public health and the environment; and that site-specific remedies are cost-effective.

In conclusion, the totality of the circumstances analysis confirms that designation of PFOA and PFOS as CERCLA hazardous substances is warranted. An analysis of the advantages and disadvantages of designation, including weighing of

[58] Congress enacted CERCLA to address contaminated sites across the nation, which was considered one of ''the most serious health and environmental challenge[s] of the decade.'' S. Rep. No. 96–848, at 2 (1980). Congress acknowledged that ''the potential impact of toxic chemicals on the general public and environment through unsound hazardous disposal sites and other releases of chemicals is tremendous.'' *Id.* And in fact, expert testimony solicited by Congress stated that the breadth and scope of the effect of exposure to hazardous chemicals nearly ''extend[ed] to the entire population of the United States.'' *Id.*

[59] The hazardous substance designation is not expected to change the approach EPA uses for identifying potential NPL sites. EPA already has the authority to add PFOA and PFOS releases to the NPL. EPA evaluates a number of options before determining the most effective approach for site cleanup. Alternatives to NPL listing may include: Superfund Alternative Approach, state cleanup, cleanup by other federal agencies, EPA removal, deferral to another EPA program and various enforcement mechanisms. Therefore, releases that contain PFOA or PFOS are more likely to be addressed through non-NPL mechanisms than through the NPL. Between FY 2003 and FY 2022, only about four percent of all contaminated sites evaluated by EPA for placement on the NPL were added to it. Since 2013, EPA has, on average, added 11 non-federal sites per year to the NPL and EPA does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule.

quantitative and qualitative benefits and costs, demonstrates that the advantages outweigh the disadvantages. Further, designation best achieves CERCLA's dual objectives—the timely cleanup of contaminated sites and ensuring that those responsible pay for cleanup. Designation provides additional tools that allow for earlier, broader, more effective cleanups, allowing EPA to protect communities that are exposed to high concentrations of PFOA and PFOS.

VII. Summary of Public Comments and Responses

In this final action, EPA is designating PFOA and PFOS, including their salts and structural isomers, as hazardous substances pursuant to CERCLA section 102(a).

In response to the September 6, 2022, proposed rule (2022 Proposal), EPA received approximately 64,000 comments, including mass mail. EPA received comments from a variety of sources, including the regulated community, trade associations, and State, Tribal and local agencies. The Agency received comments generally supporting and opposing the designation of PFOA and PFOS as CERCLA hazardous substances. EPA also received a number of comments requesting clarity on the various issues that EPA considered in support of the 2022 Proposal. EPA has taken the submitted comments into consideration in preparing this final action. Comments have been summarized and EPA has provided detailed responses to the significant comments either here in this final action or in the *Response to Comments on the Designation of Perfluorooctanoic Acid (PFOA) and Perflurooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances,* which is available in the rulemaking docket. This section includes responses to a selection of the significant comments received on various topics addressed in the 2022 Proposal.

A. Legal Authority

1. Consideration of Cost and Section 102(a)

Comment: Several commenters assert that EPA must consider costs when designating a hazardous substance pursuant to CERCLA section 102(a). These commenters disagreed with EPA's proposed interpretation of CERCLA section 102(a) "as precluding consideration of costs in hazardous substance designations." Those commenters generally remarked that EPA's position is inconsistent with U.S. Supreme Court case law on considering costs in regulatory actions. Commenters that disagreed with EPA's position also generally argued in the alternative that, at a minimum, EPA has discretion to consider cost. Conversely, some commenters agreed with EPA's proposed position that CERCLA section 102(a) precludes the consideration of cost.

Commenters that disagreed with EPA's position assert that CERCLA section 102(a) requires the consideration of cost. Commenters assert that the phrase "as may be appropriate" in CERCLA section 102(a) means that EPA must consider cost in considering whether to promulgate regulations to designate hazardous substances. Commenters support this interpretation by: (1) Asserting that CERCLA provides no textual basis to preclude cost citing *Michigan* v. *EPA,* 576 U.S. 743, 752 (2015), where the court held that the phrase "appropriate and necessary" as used in section 112(n)(1)(A) of the CAA must include some consideration of cost; and (2) distinguishing *Whitman* v. *American Trucking Ass'ns, Inc.,* 531 U.S. 457 (2001), and *Utility Solid Waste Activities Group* v. *EPA,* 901 F.3d 414 (D.C. Cir. 2018), in which the courts upheld EPA determinations that health-based statutory provisions precluded consideration of costs. A few commenters further supported their position by asserting that CERCLA's definition of "hazardous substance," CERCLA section 101(14), incorporates by reference other environmental statutes with listing or identification criteria that include cost considerations.

These commenters also argued in the alternative that even if EPA is not required to consider cost, it at least has discretion to do so. Looking to the Court's decision in *Entergy Corp.* v. *Riverkeeper, Inc.,* one commenter implied that ". . . silence [as to cost] is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree." 556 U.S. 208, 222 (2009).

EPA also received comments agreeing with its proposed interpretation that CERCLA section 102(a) precludes the consideration of cost. As one commenter stated, EPA's proposed interpretation "accords with CERCLA's unambiguous text, statutory structure, and judicial interpretations of comparable provisions of other environmental laws." The commenter notes that "CERCLA's text contains a single criterion for the designation of a hazardous substance: whether the substance, 'when released into the environment[,] may present substantial danger to the public health or welfare or the environment.' " The commenter also states that "[c]ompliance costs do not constitute 'substantial danger to the public health or the environment' and are not attributed to the 'release[ ]' of a hazardous substance into the environment. . . ." The commenter contrasts CERCLA section 102(a) with other CERCLA provisions that authorize or require cost considerations to conclude that Congress intended a difference in meaning. Finally, the commenter suggests that CERCLA section 102(a) is akin to other "health-focused provisions of other environmental laws" that courts have interpreted to exclude cost considerations.

Response: EPA proposed interpreting CERCLA section 102(a) as precluding the consideration of cost in designating CERCLA hazardous substances. EPA recognizes that, as a general matter, a statutory assessment of health and environmental-based criteria like the criteria in section 102 does not generally allow for consideration of costs. As discussed in Section V of this document, examining only the statutory criteria—whether PFOA or PFOS "may present a substantial danger to public health or welfare or the environment" and without considering costs and benefits—EPA has concluded that designation is warranted.

EPA considered comments supporting and disagreeing with the position that CERCLA section 102(a) precludes the consideration of cost. In taking final action, EPA decided it need not determine whether section 102(a) precludes consideration of costs and benefits because designation is warranted either by examining the health- and environmental-based criteria alone or by examining these criteria along with the broader totality of the circumstances. The Agency first evaluated the available scientific and technical information about those substances and concluded that designation of each is warranted based solely on a finding that PFOA and PFOS may present substantial danger to public health or welfare or the environment. The Agency next conducted a separate totality-of-the-circumstances analysis, which did consider costs and benefits. EPA considered the available scientific and technical information, along with the advantages and disadvantages of designation, including quantified and unquantified benefits and costs, and concluded this analysis reinforced that designation was warranted as reflected in section VI of this preamble. Because EPA's designation is warranted when considering benefits and costs as part of a totality of the circumstances analysis, EPA need not resolve whether CERCLA

section 102(a) precludes EPA from taking into account costs.

2. Interpretation of the Phrase ''May Present Substantial Danger''

Comment: Commenters posit that the standard for designation proposed by EPA is overbroad, vague, and arbitrary and capricious. Some commenters argue that EPA's alleged vague articulation of this standard provides little guidance on how or why PFOA and PFOS satisfy that standard. Commenters go on to assert that the lack of clarity regarding EPA's proposed interpretation of ''may present a substantial danger'' suggests that the Agency has deprived the public of the ability to meaningfully comment on its proposed rule. Relatedly, these commenters state that EPA must clearly state the level of evidence that is sufficient to demonstrate ''substantial danger'' before proceeding with the designation. Commenters also asserted that EPA failed to demonstrate how PFOA and PFOS qualify as toxic, persistent, and prevalent.

Commenters also argue that EPA must address the likelihood of exposure to PFOA and PFOS in evaluating whether designation of PFOA and PFOS is consistent with section 102(a). Another commenter suggests that EPA propose a standard for designating substances consistent with 102(a) in a separate rulemaking before proceeding with designating any substances.

Commenters further claim that the standard EPA articulated makes it unclear how EPA may apply CERCLA section 102(a) in the future to designate additional substances. A commenter asserts that EPA has not identified an ''intelligible principle'' to apply when making listing decisions, and therefore, any level of risk is sufficient to support a listing of a chemical so long as it is also mobile, persistent, and prevalent. Commenters also argue that there should be a level of predictability for potential future designations; for example, EPA should identify a bright-line risk threshold at which a substance poses ''substantial danger'' for the purposes of section 102(a). One commenter suggests that EPA must explain the characteristics that a substance must exhibit to be designated as a hazardous substance under section 102(a). Another commenter stated that the criteria articulated for CERCLA section 102(a) should have a level of specificity similar to the criteria for listing decisions made under the environmental statutes incorporated by reference through CERCLA's definition of hazardous substances.

Several commenters also suggest that EPA's interpretation of ''substantial danger'' for the purposes of CERCLA section 102(a) is inconsistent with a reading of that phrase offered by EPA in an Advanced Notice of Proposed Rulemaking released on January 14, 2021. Finally, one commenter argues that EPA should explain how ''substantial danger'' aligns with the NCP's risk thresholds for cancer and noncancer risks.

Response: EPA disagrees with the commenters' position that the information the Agency considered in proposing to designate PFOA and PFOS as hazardous substances under CERCLA section 102(a) was overbroad, vague, and arbitrary and capricious. In the final rule, EPA identified the information it considered in evaluating whether a substance satisfies CERCLA section 102(a) and described the information it considered in reaching its conclusion that PFOA and PFOS satisfy CERCLA section 102(a). Specifically, as detailed in section IV.A., the two primary factors the Agency considered in the context of CERCLA section 102(a)—hazard, and fate and transport—are consistent with other statutory methodologies used for identifying CERCLA hazardous substances. Under section 102(a) of CERCLA, EPA has been delegated the authority to identify and weigh information relevant to determining whether a substance, when released, may present a substantial danger and the approach we have adopted is reasonable and consistent with EPA's other authorities. In the final rule, EPA also conducted an additional, discretionary analysis of the totality of the circumstances.

EPA also disagrees with commenters that EPA should identify a bright-line risk threshold at which a substance poses ''substantial danger'' for the purposes of section 102(a). The plain language of CERCLA section 102(a) does not require a ''bright-line'' risk threshold applicable to any and all substances. Further, the Agency does not know how it would establish such a line, including because exposures at different levels are associated with a variety of health effects, carcinogenic and non-carcinogenic risk are calculated separately, risk must consider, acute, sub-chronic, and chronic exposure, and risk is calculated for all site contaminants combined,[60] and the commenters do not provide suggestions for how such an approach would work. Instead, EPA is utilizing the discretion provided in CERCLA section 102(a) to conduct individual analyses of substances that account for all of their characteristics to determine whether, when released, the substances may present substantial danger. Moreover, EPA also finds that a bright-line test is not appropriate because the plain language of CERCLA section 102(a) (''may present a substantial danger'') does not require certainty that a release of a substance in fact presents a substantial danger in any given location it is found.

EPA disputes the commenter's position that the NCP's risk thresholds for cancer are relevant to its interpretation of whether PFOA or PFOS may present a substantial danger to public health or the environment under section 102(a) of CERCLA. EPA's cancer risk thresholds are used on a site-specific basis—during EPA's remedy selection process—to take into account an individual's lifetime cancer risk. By contrast, the analysis of whether a substance ''may present a substantial danger'' for the purposes of designation as a CERCLA hazardous substance does not require certainty and is not site-specific. It would be inconsistent with the plain language of section 102(a) for EPA, at this stage and for the purpose of designating hazardous substances, to evaluate the specific releases in which exposure to PFOA and PFOS pose actual risk. Those determinations are left for later stages in the CERCLA process and evaluated on a site-by-site basis.

EPA also rejects the commenter's assertion that CERCLA section 102(a) requires the Agency to promulgate a standard for designating hazardous substances in advance of today's action. CERCLA section 102(a) includes no such requirement, and neither do the other environmental statutes that authorize EPA to list or designate substances as hazardous. Rather, CERCLA section 102(a) provides that, ''[t]he Administrator shall promulgate and revise as may be appropriate, regulations *designating* . . . hazardous substances . . .'' CERCLA section 102(a) (emphasis added). This language is distinct from other places in CERCLA where Congress directed EPA to promulgate regulations or procedures for various CERCLA activities. For example, CERCLA section 112 explicitly provides that EPA shall ''prescribe appropriate forms and procedures'' for filing CERCLA claims. CERCLA section 112(b)(1). Likewise, CERCLA section 105 directs EPA to ''establish procedures and standards for responding to releases of hazardous substances.'' CERCLA section 105(a). Section 102(a) does not include similar

[60] USEPA. 1986a. *Guidelines for the Health Risk Assessment of Chemical Mixtures.* EPA 630–R–98–002. Available on the internet at: *https://www.epa.gov/risk/guidelines-health-risk-assessment-chemical-mixtures.*

language and does not require that EPA promulgate a standard for designating hazardous substances in advance of doing so. Nonetheless, EPA identified two primary factors—hazard, as well as fate and transport—relevant to the designation of hazardous substances. To further inform its decision, EPA concluded that other information may be relevant to evaluating releases of the substance, such as the frequency, nature, and geographic scope of releases of the substances and likelihood of exposure. EPA's evaluation of the scientific and technical information pertaining to those factors support the Agency's finding that both PFOA and PFOS may present substantial danger to public health and the environment.[61]

EPA further disagrees with the commenter's claim that Congress failed to provide an ''intelligible principle'' to guide EPA's authority to designate hazardous substances pursuant to section 102(a) of CERCLA. The non-delegation doctrine provides that ''Congress generally cannot delegate its legislative power to another Branch.'' *Mistretta* v. *United States,* 488 U.S. 361, 371–72 (1989). This test requires that Congress ''lay down by legislative act some intelligible principle'' to which the recipient must conform. *Id.* (quoting *J.W. Hampton. Jr. & Co.* v. *United States,* 276 U.S. 394, 409 (1928)). Congress's delegation of authority to EPA in the context of CERCLA section 102(a) amply satisfies the constitutional standard set forth in controlling Supreme Court precedent because Congress has clearly provided an ''intelligible principle'' in the provision limiting EPA's discretion in designating substances under the statute. Specifically, section 102(a) provides that the Agency may designate those substances which, ''when released into the environment may present substantial danger to the public health or welfare or the environment.'' 42 U.S.C. 9602(a). Contrary to the commenter's claim, the authority conferred by Congress is neither open-ended nor otherwise so imprecise as to provide no principles for the Agency to apply in designating hazardous substances. Rather, CERCLA section 102(a) requires EPA to base its designation decisions on certain specified principles, including whether the substance in question poses a substantial danger to either public health, welfare, or the environment. These considerations intelligibly confine EPA's discretion to designate substances under the statute and the Agency's listing decision is not only based upon the criteria prescribed by Congress but is firmly within the bounds of the Court's nondelegation precedents. *See, e.g., American Power & Light Co.,* 329 U.S. at 104 (upholding the authority of the Securities and Exchange Commission to modify the structure of holding company systems so as to ensure that they are not ''unduly or unnecessarily complicate[d]'' and do not ''unfairly or inequitably distribute voting power among security holders.''); *Yakus* v. *United States,* 321 U. S. 414, 420, 423–26 (1944) (approving the wartime conferral of agency power to fix the prices of commodities at a level that ''will be generally fair and equitable and will effectuate the [in some respects conflicting] purposes of the] Act.'' (internal quotations omitted); *National Broadcasting Co.* v. *United States,* 319 U.S. 190, 225–26 (1943) (finding an ''intelligible principle'' in the Federal Communication Commission's power to regulate airwaves in the ''public interest.''). In sum, CERCLA section 102(a) provides an intelligible principle that guides the Agency in the exercise of its authority under section 102(a).

EPA also disagrees with the assertion that its interpretation of ''substantial danger'' is inconsistent with its past interpretation of this phrase or EPA's interpretation of similar phrases. In the context of CERCLA section 102(a), EPA has never authoritatively issued an interpretation of ''substantial danger'' prior to this designation. In 2021, EPA issued an Advanced Notice of Proposed Rulemaking (ANPRM) seeking comment and data to assist in the consideration of the development of future regulations pertaining to PFOA and PFOS. *See Addressing PFOA and PFOS in the Environment: Potential Future Regulation Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act* (Jan. 14, 2021). The ANPRM represented a preliminary effort by the Agency to obtain public input on certain issues to inform its thinking on any future proposed rulemaking regarding PFAS. EPA never received feedback on the ANPRM's discussion of ''substantial danger'' as the document was withdrawn shortly after it was issued and never published in the **Federal Register**. Since that time, the Agency has proposed an interpretation of section 102(a) and solicited and obtained comments through this rulemaking process that have informed the development of EPA's final interpretation of ''substantial danger.''[62]

As EPA explained in section IV.A., the Agency's interpretation of CERCLA section 102(a) is consistent with the proposed rule and in harmony with its application of similar language in site-specific provisions. Section 102(a) does not require certainty that the substance poses a substantial danger or require proof of actual harm when released into the environment.

EPA also disagrees with the commenters assertions that the Agency failed to substantiate EPA's conclusion that PFOA and PFOS may present a substantial danger to public health and the environment. The proposed rule established, and this final action confirms that the available scientific and technical information demonstrate that both PFOA and PFOS may present substantial danger to public health and the environment. That conclusion is supported by the scientific and technical evidence of adverse effects to human health and the environment from PFOA and PFOS exposure, their persistence and mobility in the environment, and the significant potential for human exposure due to their prevalence in the environment.

3. Authority To Create Exclusions From the Designation

Comment: Several commenters suggest that section 102(a) grants EPA authority to create exclusions from designation for certain uses of or materials containing PFOA and PFOS. According to one commenter the phrase ''as may be appropriate'' in section 102(a) grants EPA broad authority to include and exclude substances from a designation. Commenters also argue that CERCLA's definition of ''hazardous substance'' in section 101(14) supports this interpretation. CERCLA section 101(14) incorporates substances or chemicals regulated under select provisions of the CWA, RCRA, CAA, and TSCA, and at least some of those statutory provisions include exclusions;

[61] To support EPA's finding in this final rule that both PFOA and PFOS each individually pose a human health hazard, EPA gave weight to immunological, hepatic, developmental, cardiovascular, and cancer effects. These health outcomes had the strongest evidence of associations between PFOA and PFOS exposure and adverse health effects.

[62] Both interpretations of 102(a)—the preliminary interpretation offered in the 2021 ANPRM and today's final rule—allow for consideration of similar information to assess whether a release into the environment may present substantial danger. Hazard can encompass ''the degree of danger posed;'' fate and transport can encompass temporal considerations as in whether a substance remains in the environment ''more than fleeting in terms of time;'' and the consideration of additional information may include a consideration of the ''geographic scope'' of the substance in the environment. The standard that EPA is affirming today more accurately describes the type of scientific information needed to consider whether a substance, when released in the environment, may present substantial danger.

therefore, according to commenters, Congress would have expected EPA to have the authority to create exclusions pursuant to a CERCLA 102(a) designation.

Some commenters suggested that EPA can create exclusions that mirror other exclusions or defenses in CERCLA. For example, some commenters suggested that application of biosolids should be excepted from designation consistent with CERCLA's definition of release in section 101(22), which excludes ''the normal application of fertilizer.'' Another commenter suggested that EPA create an exclusion that reflects the liability defense in CERCLA section 107(d) for government ''actions taken in response to an emergency created by the release . . . of a hazardous substance generated by or from a facility owned by another person.''

Commenters requested that EPA create exclusions for: (1) paper mill residuals that are beneficially land applied as a fertilizer or soil conditioner; (2) land application of municipal biosolids; and (3) PFOA and PFOS contained in AFFF used in response to a fire or other emergency. Another commenter suggested that EPA should only designate PFOA and PFOS contained in specific mixtures or compounds generated by specific sources.

Some commenters suggest that an exclusion for certain materials or uses of PFOA and PFOS is necessary to avoid unintended consequences from the designation or over-broad impacts. For example, commenters expressed concern that designating PFOA and PFOS would result in liability for entities, such as farms applying biosolids or airports using AFFF for fire-fighting activities in emergency situations, that should not bear responsibility for generating or creating the contamination. Finally, one commenter claimed that CERCLA should not be used to designate PFOA and PFOS because designation will have the end-result of negatively impacting ''good actors.''

Response: EPA declines to create exclusions for certain uses of PFOA and/or PFOS in this rulemaking. EPA believes there is a strong argument that section 102(a) does not authorize exclusions for certain uses of a substance where EPA has concluded that the substance (here, PFOA and PFOS) may present substantial danger to the public health or welfare or environment, based on its review and analysis of a significant body of scientific and technical information. In this circumstance, EPA believes that section 102(a) is best read to preclude exclusions for certain uses of PFOA and PFOS—relative to other uses—without a factual or scientific basis showing that a particular use does not meet the standard articulated by Congress. *See* CERCLA section 102(a) (authorizing EPA to designate substances that, when released into the environment, ''may present substantial danger to the public health or welfare of the environment''). Even if EPA had authority to create exclusions for certain uses, it lacks the basis to do so here. Commenters did not provide information or data to support a conclusion that certain types of releases of PFOA and PFOS do not present a substantial danger, including an exclusion for AFFF as used for fire-fighting purposes and an exclusion for PFOA and PFOS contained in biosolids or soil amendments.[63] Given EPA's conclusion that PFOA and PFOS do present a substantial danger, and in the absence of evidence that certain releases of PFOA and PFOS do not present a substantial danger to public health or welfare or the environment, EPA lacks a scientific or factual basis for the exclusions requested.

Commenters also did not provide a persuasive justification for EPA to otherwise carve out specific uses of PFOA and/or PFOS from this designation irrespective of scientific or factual evidence relative to potential public health and environmental impacts. Commenters appear to be proposing that EPA create an exclusion to liability via CERCLA section 102(a); the Agency, however, does not believe that section 102 is the appropriate mechanism to establish liability exclusions, and EPA questions whether it has the authority to do so, through this provision. For example, the D.C. Circuit has held that, in enacting CERCLA, Congress reserved resolution of liability issues to the judiciary, not the Agency.[64] *See Kelley* v. *EPA,* 15 F.3d 1100, 1108 (D.C. Cir. 1994) (''Congress . . . has designated the courts and not EPA as the adjudicator of the scope of CERCLA liability.''). Congress explicitly identified CERCLA's liable parties in section 107. In fact, Congress has enumerated many exclusions to CERCLA's liability scheme over the years—and courts have regularly interpreted and applied those provisions. For example, CERCLA section 107(d) provides a mechanism to account for liability concerns arising out of an emergency response, which appears similar to one commenter's request for an exclusion for the use of AFFF in response to an emergency. *See, e.g.,* CERCLA section 107(d)(1)–(2) (providing a defense to costs and damages in the event of an incident creating danger to public health or in the event of an emergency).). EPA believes this Congressionally-established framework, discussed in further detail below, is more appropriate for the type of exclusions that commenters suggest.

EPA also concludes that the commenter's request for an exclusion for the application of biosolids containing PFOA or PFOS is not appropriate for resolution in this rulemaking under section 102(a). Section 102(a) provides for designation of a substance that, when ''released into the environment,'' may present substantial danger to the public health or welfare or environment. CERCLA section 102(a). As stated above, EPA considered a significant body of scientific and technical information in concluding that both PFOA and PFOS—irrespective of use—may present a substantial danger to public health or welfare or the environment.

Against this backdrop, EPA considered commenters' request for EPA to exclude from designation PFOA and PFOS when contained in biosolids consistent with the language in CERCLA section 101(22). EPA acknowledges that the CERCLA definition of ''release'' explicitly excludes the ''normal application of fertilizer.'' CERCLA section 101(22)(D). EPA believes this language is best read as requiring a site-specific analysis and that a categorical exclusion for all contaminated biosolid application using section 102(a) risks exceeding the limits of the exclusion as envisioned by Congress. *See, e.g., Sierra Club, Inc.* v. *Tyson Foods, Inc.,* 299 F. Supp. 2d 693, 714 (W.D. Ky. 2003) (defendant did not qualify for the normal application of fertilizer

[63] EPA received requests for exclusions from liability from specific sectors—namely, water utilities, municipal landfills, local governments, landowners or utilities that land apply biosolids or paper mill sludge, and landowners adjacent to offsite sources—for the use of certain materials (*i.e.,* biosolids), and for the disposal of particular types of waste, including landfill leachate, research waste, and medical waste. However, the commenters did not present data supporting their claims that certain releases, either from specific types of entities, uses, or kinds of waste, do not present a substantial danger to public health, welfare, or the environment.

[64] Although a court is the final arbiter of whether a party is liable under CERCLA section 107, EPA intends to develop a policy that explains the Agency's priorities for CERCLA enforcement in the context of PFOA and PFOS releases. Enforcement discretion policies are not exclusions from liability but instead describe circumstances in which the Agency may exercise its discretion to not pursue enforcement actions against certain parties that may fall within a category of liable parties under CERCLA section 107. EPA's enforcement discretion is guided by the unique circumstances of each case.

exemption because it was not applying ammonia to farm fields as fertilizer when it vented the ammonia into the atmosphere); *City of Waco* v. *Schouten,* 385 F. Supp. 2d 595, 602 (W.D. Tex. 2005) (defendants' agricultural practices (namely, the improper storage and maintenance of manure waste storage areas) did not fall within the ''normal application of fertilizer'' exclusion)). EPA also does not believe an exclusion under section 102(a) is necessary, because it would be duplicative of the exclusion in section 101(22)(D). And because liability under CERCLA section 107 is tied to a ''release'' or threat of a ''release,'' any entity facing potential liability for the application of biosolids contaminated with PFOA or PFOS will have the opportunity to make site-specific arguments as to whether its actions fall within the ''normal application of fertilizer'' exclusion to the definition of ''release.'' [65]

EPA also rejects the commenters' assertion that creating an exclusion for this designation is necessary to address concerns regarding over-broad or unintended liability, such as for farmers or water utilities. Designation does not alter CERCLA's liability framework, which EPA expects to continue to operate as it has for decades to equitably resolve who should pay, or automatically confer liability. First, potential plaintiffs must establish a legal basis for CERCLA liability; to recover costs from the parties responsible for contamination requires a plaintiff to show that a ''release'' or ''threatened release'' of a ''hazardous substance'' from a ''facility'' has caused it to incur cleanup costs. CERCLA section 107(a). The defendant must also fall within at least one of four classes of covered persons: (1) the owner or operator of the facility, (2) the owner or operator of the facility ''at the time of disposal'' of hazardous substances, (3) persons who ''arranged for disposal'' or treatment of hazardous substances, and (4) certain transporters of hazardous substances. *Id.*

Although liability under CERCLA section 107(a) is strict, subject only to a few limited defenses specified in section 107(b), it is not unlimited, and courts may decide to apportion costs among defendants where the harm is divisible and there is a reasonable basis for doing so. *Burlington N.,* 556 U.S. at 613–15. Further, if a defendant is found jointly and severally liable for response costs under CERCLA section 107(a), the defendant may also seek contribution from other potentially responsible parties pursuant to CERCLA section 113(f).

In addition, CERCLA provides defenses to and exemptions from Superfund liability for certain parties that are otherwise liable. For example, under CERCLA section 107(b), liability is limited in situations in which the release or threat of release of a hazardous substance was caused by an act of God, an act of war, or an act or omission of a third party (or some combination thereof). CERCLA section 107(b)(1)–(4). CERCLA also contains several statutory limitations on liability, which are more fully described in section VI.B. These include liability exemptions for contiguous property owners, innocent landowners under certain circumstances, de minimis or de micromis parties, and ''federally permitted'' releases, among others. And a party may not be subject to CERCLA at all if the release is considered a ''normal application of fertilizer.'' EPA also notes that—as detailed in section VI.B.—it has well-established enforcement policies that help the Agency prioritize sites that pose the most risk.

Finally, the commenters' concerns regarding liability do not account for the intervening steps between designation and site-specific cleanup or enforcement decisions. A designation alone does not require EPA or others to take response actions, does not require any response action by a private party, and does not determine liability. Response actions are contingent, discretionary, and site-specific decisions that are made after a hazardous substance release or threatened release. Site-specific decisions are also the more appropriate opportunity to evaluate unacceptable risk posed by specific releases, rather than a blanket exclusion for certain uses or PFAS-containing materials that may not account for site-specific risk.

The first steps in the CERCLA process are to identify a release, investigate the scope and extent of such a release, and evaluate its potential risk to human health and the environment. CERCLA is a largely discretionary statute that gives EPA leeway to determine whether, after that investigatory stage, it is appropriate to move forward with a cleanup. CERCLA speaks to this evaluation of releases and risk. For example, Congress provided that EPA shall identify ''criteria for determining priorities among releases or threatened releases throughout the United States for the purpose of taking remedial action and, to the extent practical taking into account the potential urgency of such action, for the purpose of taking removal action.'' CERCLA section 105(a)(8)(A). CERCLA goes on to provide that ''[c]riteria and priorities . . . shall be based upon relative risk or danger to public health or welfare or the environment . . . taking into account to the extent possible the population at risk, the hazard potential of the hazardous substances at such facilities, the potential for contamination of drinking water supplies, the potential for direct human contact,'' among other considerations embodied in the NCP. The NCP provides guidance on when it may be appropriate to cleanup releases either through a removal or remedial action. For example, for removal actions, the NCP provides that the lead agency may take action when the agency has determined ''that there is a threat to public health or welfare'' based on a set of factors such as actual or potential exposure to drinking water supplies, the potential for hazardous substances to migrate, and the availability of other appropriate Federal or State response mechanisms to address the release. 40 CFR 300.415(b).

Even if EPA determines that it is appropriate to move forward with a cleanup and a site is listed on the NPL, a listing does not require any immediate action. Rather, an NPL listing is the initial step towards a potential long-term remedy for a site. Listing also allows EPA to prioritize which sites warrant further investigation to better understand potential risks to human health and the environment. This process identifies less than 10% of CERCLA sites as NPL sites.

Only after those very careful and deliberative steps to investigate and prioritize sites does EPA begin the process of identifying potential cleanup actions. Because of this significant narrowing of sites that will receive EPA attention, it follows that not every instance of contamination by a hazardous substance—including a PFOA and/or PFOS release—will lead to enforcement and liability. And, as previously noted, EPA has a long history of focusing its enforcement on significant polluters, potentially further narrowing the extent of liability. While there may be independent third-party cleanups, those too are not immediately triggered by designation and just like with EPA-focused cleanups, parties

[65] Not all releases warrant response under CERCLA, and not all release lead to litigation and liability for all PRPs. Whether a party may be exposed to any liability in the first instance is ultimately a function of whether a response action is taken to address the release. As an initial matter, EPA has discretion to determine whether to respond to a release and only responds to those releases that pose unacceptable risk to human health and the environment. Even then, EPA may assess relative risk among releases to determine which releases should be prioritized for investigation and, potentially, clean up. Further, whether a PRP may be pursued for costs, found liable by a court, and required to pay some portion of costs remain uncertain for any given release.

would typically have the benefit of CERCLA's liability protections, equitable divisions of responsibility by the courts, and so forth.

EPA also notes that concerns about the cost of liability, the cost of cleanup, and the costs that certain facilities will bear managing PFOA and PFOS in waste to mitigate CERCLA liability risk are costs that Congress had front of mind in enacting CERCLA and chose to proceed anyway. The statutory language of CERCLA clearly provides interconnected response, enforcement and liability authorities that impose costs on PRPs enumerated in the statute. First, CERCLA section 104(a) authorizes EPA to respond to a release (or substantial threat of a release) of a hazardous substance into the environment, or of a pollutant or contaminant that may present an ''imminent and substantial danger to the public health or welfare.'' CERCLA section 104(a). In addition, CERCLA section 106 gives EPA the authority to compel action by liable parties in response to a release or threatened release of a hazardous substance that may pose an ''imminent and substantial endangerment'' to public health or welfare or the environment. CERCLA section 106(a). Finally, under CERCLA section 107, when the United States, states, or Tribes perform cleanup work and incur costs, section 107(a) authorizes them to recover those costs from potentially responsible parties. *See* CERCLA section 107(a).

Legislative history also shows that one of Congress' aims was to incentivize better waste management practices: ''In correcting the historic neglect of hazardous substances disposal, it is essential that this incentive for greater care focus on the initial generators of hazardous wastes since they are in the best position to control the risks. Generators create the hazardous wastes, they have more knowledge about the risks inherent in their wastes and how to avoid them, and they determine whether and how to dispose of these wastes.'' S. Rep. No. 96–848, at 14 (1980). Congress' expectation was that better waste management practices could ultimately result in cost savings by reducing the need for expensive remedies to clean up hazardous waste in the environment: ''Expenditures to prevent a threatened release, discharge, or disposal may be necessary if damages are to be avoided while also providing considerable savings when compared to the costs of removal after a release, discharge or disposal has occurred.'' *Id.* Ultimately, Congress' calculation was that the benefit to human health and the environment to prevent exposure to hazardous chemicals is worth the costs borne by industry to improve waste management practices, prevent releases, and minimize the costs of retroactive efforts to clean up hazardous waste.

EPA concludes that it would be inappropriate to carve out certain uses or materials containing PFOA or PFOS from the designation because any PFOA or PFOS release ''may present substantial danger,'' and subsequent steps in the CERCLA process are more appropriate for determining whether any specific release poses risk sufficient for further investigation and, potentially, cleanup.

4. Designating PFOA and PFOS as ''Hazardous Substances'' Under CERCLA Section 102(a) Does Not Present a ''Major Question''

Comment: Commenters contend that EPA's use of section 102(a) of CERCLA to designate PFOA and PFOS as hazardous substances—as well as the Agency's interpretation of the scope of the authority granted by this provision—run afoul of the ''major questions doctrine'' articulated by the Supreme Court in *West Virginia* v. *EPA,* 142 S.Ct. 2587 (2022). To support this assertion, the commenters argue that the designation will have a substantial ''economic, social, and legal impact'' and point to the fact that EPA is utilizing section 102(a) of CERCLA for the first time to contend that today's action represents a novel and transformative expansion of the Agency's regulatory authority.

Response: EPA disagrees that this rulemaking raises a major question as defined in *West Virginia* v. *EPA,* 142 S. Ct. 2587 (2022).

The designation of PFOA and PFOS pursuant to section 102(a) of CERCLA does not represent a radical change to CERCLA's statutory scheme. Rather, the designation is well within the statutory framework that Congress provided. CERCLA by its express terms authorizes EPA to designate hazardous substances and the designation is consonant with the Agency's longstanding practice of adding other chemicals to CERCLA's hazardous substances list through CERCLA's ''automatic'' designation process in section 101(14). That provision cross-references listing authorities in the CAA, CWA, RCRA, and TSCA. CERCLA's automatic designation process has resulted in the addition of more than 800 hazardous substances to the statute's list of hazardous substances through separate actions. And just like it did when making designations under those other statutes, here EPA examined scientific and technical factors, including hazard and fate and transport, when evaluating whether PFOA and PFOS met the statutory standard and may present substantial danger to the public health or welfare or the environment. *See supra-Section IV.* Further, as discussed in Section VI.B, PFOA and PFOS are not different in kind from the other substances added to CERCLA's hazardous substance list.

While EPA's action today utilizes a different mechanism for designation than the procedure outlined in CERCLA section 101(14)—which defines the term ''hazardous substance'' by reference to provisions in other environmental statutes and to substances designated under CERCLA section 102—Congress specifically provided EPA with multiple pathways to address the varied threats posed by hazardous substances in various media. Although the commenters argue that EPA's approach to PFOA and PFOS represents an unprecedented expansion of EPA's authority, EPA has added similarly ubiquitous substances to CERCLA's hazardous substance list for decades. For example, polychlorinated biphenyls (PCBs) became hazardous substances when EPA initially promulgated its list of hazardous substances on April 4, 1985, *Notification Requirements; Reportable Quantity Adjustments,* 50 FR 13456, 13475 (1985), and are generally considered ''ubiquitous contaminants in the environment.'' Rouzbeh Tehrani and Benoit Van Aken, *Hydroxylated Polychlorinated Biphenyls in the Environment: Sources, Fate, and Toxicities,* 21 Environmental Science and Pollution Research, 6334–6345 (2014); see also U.S. Dept. of Health and Human Services, *Toxicological Profile for Polychlorinated Biphenyls (PCBs),* at 291 (November 2000) (''PCBs are ubiquitous and continuously circulating in the global environment. . . .''); U.S. Environmental Protection Agency, *Remediation of PCBs at Superfund Sites,* at 7 (2001) (noting that as of publication ''[o]f the 1,229 Superfund sites currently on the NPL, PCBs have been detected at 357 sites.''). PCBs, however, are far from the only highly prevalent contaminant of concern that EPA has routinely grappled with at Superfund sites for decades. In fact, at the 1,548 Superfund sites with a selected remedy, arsenic has been identified at 919 facilities, lead at 897, benzene at 885, and trichloroethene at 816. *See* U.S. Environmental Protection Agency, *Contaminant of Concern Data for Decision Documents by Media, fYs 1982–2021 (Final NPL, Deleted NPL, and Superfund Alternative Approach Sites)* (2024), available at *https://*

www.epa.gov/superfund/superfund-data-and-reports. Ultimately, EPA's decision to designate PFOA and PFOS under section 102(a) is not an expansion of the Agency's authority that would cause a ''radical'' or ''fundamental'' shift in CERCLA's statutory scheme.

For these reasons, EPA's regulatory action to designate PFOA and PFOS as CERCLA hazardous substances does not present a major question.

B. Operation of CERCLA

1. Comments Suggesting That Other Authorities Are Better Suited To Address PFAS Contamination

Comment: Several commenters argued that CERCLA is not the appropriate tool to address PFOA and PFOS in the environment. Commenters also argued that EPA already possesses the authority to protect public health, welfare, and the environment from any potential risks posed by PFOA and PFOS without designating these substances as hazardous under section 102(a). Instead, these commenters contend that EPA should utilize existing tools under SDWA, RCRA, CWA, and other laws to address PFAS-contaminated sites.

Multiple commenters also argued that EPA should not use CERCLA to designate PFOA and PFOS as hazardous substances because the Agency has not yet regulated PFOA and PFOS under other statutes (*e.g.,* CWA, RCRA, SDWA), and accordingly—because CERCLA site cleanup standards and responsibilities are informed by other statutes' regulatory frameworks—potentially responsible parties lack the necessary structure to conduct CERCLA cleanups of PFOA and PFOS.

In arguing that CERCLA is not the appropriate tool to address the problem posed by PFOA and PFOS, one commenter also specifically claimed that the statute was designed to address only inactive hazardous waste sites and facilities impacted by groundwater plumes contaminated by specific hazardous substances, rather than ''problematic class[es] of chemicals with widespread contamination across the country.'' Another commenter stated that it appears ARARs do not yet exist and urges EPA to delay this rulemaking until such standards are developed.

Response: EPA disagrees with the commenters' position that CERCLA is not the appropriate tool to address the challenges posed by PFOA and PFOS contamination. Congress enacted CERCLA to provide EPA with the ability to timely clean up contaminated sites that pose risk to human health and the environment. CERCLA is the right tool for addressing wide-spread, existing PFOA and PFOS contamination, which is a nationwide concern. CERCLA includes authorities to investigate and scope releases to better understand the extent of contamination. CERCLA includes response authority to implement short-term and long-term actions to address contamination and risks to public health and the environment. CERCLA removal authority is available to address emergency situations, such as when immediate action is necessary to mitigate consumption of contaminated drinking water. It also includes authority to take remedial actions that are designed to provide a more permanent remedy to mitigate or reduce unacceptable risk from highly contaminated sites. CERCLA also provides mechanisms to ensure that those responsible for the contamination pay to clean it up rather than using Fund resources. By designating PFOA and PFOS as CERCLA hazardous substances, EPA can utilize the full suite of CERCLA tools to address contamination.

CERCLA is the best tool to address the legacy of sites contaminated with these substances and to address additional releases of these chemicals in the future. As EPA noted in its Strategic Roadmap, ''[t]he risks posed by PFAS demand that the Agency attack the problem on multiple fronts at the same time. EPA must leverage the full range of statutory authorities to confront the human health and ecological risks of PFAS.'' The Roadmap looked at a variety of authorities to address PFAS, including TSCA, SDWA, CWA, RCRA, and CAA, and identified CERCLA as a tool to accomplish one of its three central directives: Research, Restrict, Remediate. CERCLA is applicable to address all environmental media: air, surface water, groundwater, and soils. And CERCLA can apply to any type of industrial, commercial, or noncommercial facility, regardless of whether there are specific regulations that affect that type of facility or how that facility might affect the environment.

The Agency also disputes the commenters' assertion that designation under CERCLA is premature in the absence of pre-existing regulatory standards for PFOA and PFOS. The plain language of CERCLA section 102(a) includes no such explicit limitation. The statute requires only that EPA determine that a substance ''may present substantial danger to public health or welfare or the environment'' to designate. Considering the significant, and growing, body of evidence that PFOA and PFOS, when released in the environment, may present substantial danger, designation is warranted. Such a limitation also runs counter to the ''automatic'' designation that occurs through CERCLA section 101(14) when a substance is identified as toxic or hazardous under another statutory authority. When a substance is designated pursuant to the specified CWA, CAA, RCRA, and TSCA authorities, there aren't necessarily pre-existing regulatory standards for that substance. For example, a substance could be listed under RCRA as a regulated hazardous waste, but not be subject to regulatory standards under the Clean Water Act or the Safe Drinking Water Act. The absence of such a regulatory framework is not a bar to listing under RCRA and nor should such a limitation be read into CERCLA section 102(a).

EPA also disagrees that, at present, there is no regulatory framework in place that allows EPA to respond effectively to PFOA and PFOS releases. While it is true that PFOA and PFOS regulations, environmental standards, and remediation technologies are evolving, CERCLA and the NCP provide a process to identify cleanup standards on a site-by-site basis that ensure that a remedy is protective of human health and the environment. CERCLA section 121(a) provides that a remedial action must be ''protective of human health and the environment.'' All remedies selected must satisfy that requirement. Cleanup standards often help define remedy protectiveness. CERCLA cleanup standards are generally those standards that are determined to be ''applicable or relevant and appropriate requirements'' (ARARs).[66] ARARs are Federal, or more stringent State, standards, requirements, criteria, or limitations. CERCLA section 121(d)(2)(A). ARARs apply to hazardous substances or pollutants and contaminants that remain on-site at the completion of a remedy. A final remedy must attain ARARs by the completion of the remedy, unless compliance with the ARAR is waived. CERCLA section 121(d)(2)(A), (d)(4). ARARs frequently are determinant in establishing preliminary remediation goals, which become site cleanup levels.

The current regulatory landscape for PFOA and PFOS is sufficient to inform future remedies, and regulatory actions to address PFOA and PFOS are

[66] The NCP provides that *Fund-financed* removal actions (*or removals under CERCLA section 106*) must comply with ARARs to the extent practicable considering the exigencies of the situation. 40 CFR 300.415. For the sake of discussion, EPA's response focuses on compliance with ARARs in the remedial context.

increasing. Currently, there are certain Federal standards that may be considered as ARARs. For example, a potential ARAR for drinking water cleanups may be the final PFOA and PFOS MCLs. For PFOA and PFOS, the MCLs are 4.0 parts per trillion (PPT) each. A number of States have also promulgated cleanup numbers for PFOA and PFOS, which may be evaluated as potential ARARs at sites. For example, Pennsylvania [67] promulgated an MCL of 14 ppt for PFOA and 18 ppt for PFOS. In addition, New Jersey [68] has adopted an MCL of 14 ppt for PFOA and 13 ppt for PFOS (*NJ DEQ, 2023*).

There are also non-chemical specific ARARs that may be relevant to a potential remedy. Those include ''location-specific'' and ''action-specific'' ARARs. Location-specific ARARs are restrictions placed on the concentration of hazardous substances or the conduct of activities solely because they are in specific locations. Some examples of specific locations include floodplains, wetlands, historic places, and sensitive ecosystem habitats. An example of a location-specific requirement is the substantive CWA section 404 prohibitions regarding unrestricted discharge of dredged or fill material into wetlands. Action-specific ARARs are usually technology- or activity-based requirements or limitations on actions taken with respect to hazardous wastes. These requirements are triggered by particular remedial activities that are selected to accomplish a remedy. Examples of action-specific ARARs include activities such as ground-water diversion, dredging, and landfill closure with waste in place.

EPA has also developed an *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Materials Containing PFAS-Substances—Version 2 (2024),* which outlines the current science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials from non-consumer products, along with screening methods to assess vulnerable populations near destruction and disposal sites. In sum, the evolving regulatory landscape with respect to PFOA and PFOS cleanup standards is not a barrier to designation nor is it a barrier to evaluating, identifying, and selecting protective remedies. The Agency is also striving to ensure regulatory actions do not overlap with one another and duplicate efforts. EPA also disagrees with the commenter's claim that CERCLA is designed solely to address inactive hazardous waste sites and facilities subject to groundwater contamination from specific contaminants of concern. The commenter's view of CERCLA runs counter to the plain language of the statute. CERCLA's language does not include any limitation on response authority to only ''inactive'' waste sites. Rather, CERCLA makes clear that authority extends to inactive and active ''facilities.'' CERCLA defines a facility as ''any building, structure, equipment, pipe or pipeline (including any pipe into a sewer or publicly owned treatment works) . . . .'' CERCLA section 101(9)(A). Moreover, CERCLA provides authority to respond to past, current, and future releases. Response authority extends to releases and the threat of release of ''any hazardous substance'' and ''any pollutant or contaminant which may present an imminent and substantial danger to public health or welfare.'' CERCLA section 104(a). CERCLA's definition of the term ''release'' also makes clear that it encompasses past and current releases. *See* CERCLA section 101(22) (defining release to include ''any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles . . .)''). This language is broad enough to encompass inactive and active sites.

Although one impetus for CERCLA was a growing concern about the public health threats posed by improperly disposed toxic waste, Congress's interest in addressing issues associated with environmental contamination was more holistic. Addressing the challenge of widespread community exposure to hazardous chemicals such as PFOA and PFOS—when released into the environment—is the exact kind of environmental threat that Congress sought to ameliorate in enacting CERCLA. Moved to action by the Love Canal incident, Congress crafted CERCLA to address contaminated sites across the nation, which it considered one of ''the most serious health and environmental challenge[s] of the decade.'' S. Rep. No. 96–848, at 2 (1980). Congress acknowledged at that time that ''more than 43,000 chemical substances are in commercial production and thousands of new ones are introduced each year . . . As a result, the potential impact of toxic chemicals on the general public and environment through unsound hazardous disposal sites and other releases of chemicals is tremendous.'' *Id.* Indeed, expert testimony solicited by Congress stated that the breadth and scope of the impact of exposure to hazardous chemicals nearly ''extend[ed] to the entire population of the United States.'' *Id.* Designating PFOA and PFOS is wholly consistent with Congress' vision for CERCLA as an important Federal tool in removing widespread toxic chemicals from the environment that have the potential to pose substantial danger to human health, welfare, and the environment.

2. Addressing PFOA/PFOS as ''Pollutants or Contaminants''

Comment: Several commenters contend that EPA should use its existing authority to address PFOA and PFOS as pollutants or contaminants rather than designate these substances as hazardous under section 102(a) of CERCLA. One commenter also argued that PFOA and PFOS must be specifically designated as pollutants or contaminants before they are designated as hazardous substances. Finally, a commenter claimed that EPA has failed to demonstrate that PFOA and PFOS qualify as pollutants or contaminants under section 101(33) of CERCLA because the Agency has not indicated why these substances ''cause or are reasonably expected to cause death, disease, physiological malfunctions, or any other conditions in the definition of 'pollutant or contaminant' in CERCLA [s]ection 101(33).''

Response: EPA disagrees with the commenters' position that the Agency should treat PFOA and PFOS contamination by relying solely on its authority to address these substances as CERCLA pollutants or contaminants. *See* CERCLA section 101(33) (defining ''pollutants or contaminants''). As EPA has explained, EPA's authority to address ''pollutants and contaminants'' is limited. Designation of hazardous substances provides the Agency with a suite of tools necessary to identify, characterize, and clean up the most contaminated sites without delay, either through PRP- or Fund-lead actions.

EPA also disagrees with the commenters that the Agency must designate PFOA and PFOS as a pollutant or contaminant under section 101(33) of CERCLA before utilizing its authority under section 102(a) to designate PFOA and PFOS as hazardous substances. Section 102(a) requires only a determination that the substance ''may present . . . substantial danger to the

[67] *https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-2/46.html.*

[68] *https://dep.nj.gov/pfas/standards/.*

public health or welfare or the environment'' when released into the environment. Moreover, a substance's status as a pollutant or contaminant is determined on a site-specific basis. And, in fact, EPA has already identified and treated PFOA and PFOS as pollutants and contaminants at multiple Superfund sites, including the Saint-Gobain Performance Plastics facility in Hoosick Falls, New York, and the Blades Groundwater site in Blades, Delaware.

The Agency further disagrees that PFOA and PFOS do not qualify as pollutants or contaminants because EPA has not shown that these substances either ''cause or are reasonably expected to cause'' human health effects. In fact, the commenter misstates the qualifying criteria for a pollutant or contaminant.

The statute requires only that pollutants or contaminants may ''reasonably be anticipated'' to impact human health. In keeping with this broad standard, multiple courts have consistently reaffirmed the principle that section 101(33) ''. . . refers to, basically, any substance which may reasonably be anticipated to cause harm'' to human health when released into the environment. *Eagle-Picher Industries, Inc.* v. *EPA,* 759 F.2d 922, 931 (D.C. Cir. 1985); *see also APWU, et al.* v. *Potter,* 343 F.3d 619 (2d Cir. 2003) (anthrax); *Lozar* v. *Birds Eye, Inc.,* 678 F.Supp.2d 589 (W.D. Mich. 2009) (iron, manganese, arsenic, chloride, and sodium); *Jastram, et al.* v. *Phillips Petroleum Co., et al.,* 844 F. Supp. 1139 (E.D. La. 1994) (produced water). PFOA and PFOS readily meet the definition of pollutants or contaminants, particularly given the weight of scientific evidence—as discussed in section V—indicating that exposure to PFOA and PFOS is associated with a host of negative health effects. Accordingly, EPA has determined PFOA and PFOS to be pollutants or contaminants on a site-specific basis, further demonstrating that PFOA and PFOS satisfy the definition in section 101(33) of CERCLA.

3. Relationship Between SDWA and CERCLA

Comment: Commenters stated that the 2022 interim Health Advisory Levels (HALs) of 0.004 ppt for PFOA and 0.02 ppt for PFOS are below the value that laboratory methods can accurately quantify, creating uncertainties with the proposed designation. Another commenter stated that EPA should provide additional clarity as to how the Agency's SDWA process will impact the setting of cleanup goals. A few commenters stated that while ''[the health advisories] are not regulations and should not be construed as legally enforceable Federal standards,'' they do shape public perception and almost certainly influence people's (including organizations') behavior. Similarly, there were comments concerning whether EPA was coordinating internally on how the SDWA rule to regulate PFOA and PFOS may impact the CERCLA program.

Response: As stated in the proposed rule, EPA did not rely on the interim PFOA or PFOS HALs or draft toxicity values as support for the proposed designation decision. EPA's 2022 interim PFOA and PFOS HALs are beyond the scope of today's action. EPA HALs are non-enforceable advisory levels that provide information to drinking water systems and officials responsible for protecting public health when emergency spills or other contamination situations occur. Based on the record before the Agency, with today's action EPA is designating PFOA and PFOS as hazardous substances.

EPA's actions establishing NPDWR for PFOA, PFOS, and other PFAS, pursuant to SDWA are beyond the scope of this action. Nonetheless, EPA has closely coordinated these actions to ensure consistency. For information about EPA's PFAS NPDWR, please see *https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit regulations.gov under docket id EPA–HQ–OW–2022–0114. The 2024 NPDWR pursuant to the Safe Drinking Water Act, EPA established a maximum contaminant level (MCL) of 4.0 ppt for both PFOA and PFOS and a maximum contaminant level goal (MCLG) of 0 ppt for both PFOA and PFOS. Consistent with CERCLA, EPA may evaluate MCLs and non-zero MCLGs as Applicable or Relevant and Appropriate Requirements (ARARs) cleanup levels on a site-specific basis. 42 U.S.C. 9621(d).

For any Superfund site, EPA evaluates the risk and determines the appropriate cleanup level for the site, including for PFOA and PFOS. The risk is evaluated according to guidance, mainly Risk Assessment Guidance for Superfund using final toxicity information, and exposure information, and according to guidance, mainly Risk Assessment Guidance for Superfund (*https://www.epa.gov/risk/risk-assessment-guidance-superfund-rags-part*). PFOA and PFOS toxicity information used in CERCLA for any risk calculations are based on toxicity values that support EPA's 2024 NPDWR. Once a basis for action has been determined, the risk at a site has been assessed, and the need for a response action is determined, then the MCLs for PFOA and PFOS will potentially be considered as ARARs on a site-specific basis and documented in a decision document. While MCLs, MCLGs, and HAs are potentially appropriate to consider at CERCLA sites, other standards may be considered for other media evaluated at a site, such as soil, air, and biota such as fish.

C. Toxicity, Human Health Effects/Mobility, Persistence, Prevalence/Release Into the Environment

1. Data Supporting Designation

Comment: Several commenters argued that EPA has not presented sufficient information regarding the environmental and human health effects of PFOA and PFOS salts and structural isomers to support the designation of such substances as hazardous under CERCLA section 102(a). Multiple commenters contend that additional scientific study is needed prior to designation of PFOA and PFOS as CERCLA hazardous substances to enhance an understanding of the risks posed by these substances to human health and the environment.

Response: EPA believes that the available data clearly supports the conclusion that PFOA and PFOS, as well as their salts and structural isomers, present a hazard to human health and the environment. For further discussion of this issue, see Section V of this document, which describes the scientific and technical information supporting the Agency's conclusion that both PFOA and PFOS may present substantial danger to public health or welfare or the environment when released into the environment.

EPA disagrees with the commenters' position regarding the need for additional data prior to designation. As discussed in detail in Sections I and V, EPA has determined that a robust body of epidemiological and toxicological studies support the Agency's conclusion that exposure to PFOA or PFOS are associated with serious and wide-ranging adverse health effects.

Comment: Several commenters asserted that EPA could not utilize draft toxicity assessments developed as part of the PFAS NPDWR rulemaking process (draft MCLG documents) to substantiate the designation of PFOA and PFOS as CERCLA hazardous substances (See Response to Comment Document, Section 3B). Specifically, these commenters argued that the draft MCLG documents are flawed because the Science Advisory Board identified certain methodological issues with the initial approaches the Agency used to derive PFOA and PFOS MCLGs. Relatedly, one commenter also

challenged EPA's purported reliance on interim Health Advisories (HAs) issued by the Agency in 2021, arguing that the underlying toxicity assessments supporting the interim HAs are flawed and have not been finalized by the Agency.

Finally, several commenters critiqued the reliability of several studies cited by EPA as part of this rulemaking, including certain epidemiological studies conducted in the Faroe Islands that EPA used to develop non-cancer toxicity values (reference doses) in the draft MCLG documents.

Response: As an initial matter, EPA disagrees with the commenters' characterization of the Agency's reliance on the draft MCLG documents and Interim HAs. EPA considered the peer-reviewed scientific studies underlying the toxicity assessments supporting the draft MCLG documents and the interim HAs as part of the Agency's comprehensive evaluation of available scientific information regarding the human health and environmental effects of exposure to PFOA and PFOS. To that point, as delineated in Section V, EPA considered hundreds of peer-reviewed publications in determining that exposure to PFOA or PFOS, when released into the environment, may present a substantial danger to the public health or welfare or the environment, including the 2016 EPA Health Effects Support Documents for PFOA and PFOS, the 2021 ATSDR Toxicological Profile for PFAS, and numerous peer-reviewed epidemiological and toxicological studies (*ATSDR, 2021; U.S. EPA, 2016c, 2016d*).

Secondarily, while beyond the scope of today's action, because these documents were finalized in 2024 as part of a separate, unrelated rulemaking after undergoing a robust peer-review and public comment process EPA rejects the commenter's assertion that the draft MCLG documents are inherently flawed because of issues identified by the Science Advisory Board (SAB). The Agency's final toxicity assessments reflect recommendations from both the Science Advisory Board (SAB) and the public comment process and address the SAB PFAS Review Panel's recommendations to improve the transparency of EPA's systematic review process. Additionally, EPA updated and expanded the protocols and methods based on SAB recommendations to improve the transparency of the process EPA used to derive the MCLGs for PFOA and PFOS and to improve consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (*U.S. EPA, 2022*). EPA followed this transparent systematic review process to evaluate the best available peer-reviewed science to conduct the PFOA and PFOS toxicity assessments (*U.S. EPA, 2024b, 2024c, 2024d*). For information on EPA's PFAS NPDWR rule, visit EPA's website at *https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit *www.regulations.gov,* under Docket No. EPA–HQ–OW–2022–0114.

EPA also disagrees with the commenter's claim that the Faroe Islands epidemiological studies fail to provide evidence of the impacts of PFOA and PFOS on vaccine response in children. The Faroe Islands epidemiological studies were peer-reviewed by the various scientific journals in which they were published. Additional studies, including one from a Greenland epidemiological study, provide support for associations between decreased vaccine response in children and exposure to PFOA and PFOS (*Timmermann et al., 2022; Zhang et al., 2023*). Additionally, the Science Advisory Board—in their ''Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS''—agreed with the selection of the critical study, *Grandjean et al.* (*2012*), that identified an association between exposure to PFOA and PFOS and suppression of a vaccine response in children exposed during development, as appropriate for the derivation of chronic RfDs[69] for PFOA and PFOS.

D. Effects of Designation

1. Reporting and Notification Requirements

a. Reportable Quantity (RQ) for PFOA and PFOS Should be Set Either Higher or Lower Than 1 Pound

Comment: Some commenters stated that EPA should lower the RQ to 0.1 pound while others expressed that the RQ should be higher than one pound. A few commenters stated that EPA should consider a RQ for cumulative releases, *i.e.,* X pounds per year. One commenter argued that EPA's proposed RQ would allow companies to release massive amounts of PFAS-containing waste before triggering any CERCLA requirements.

Response: Pursuant to CERCLA section 102, in this final rule the Agency is assigning a default RQ of one pound to PFOA and PFOS and their salts and structural isomers. The Agency believes that the statutory default RQ is appropriate in this instance because it will facilitate reliable reporting of substantial releases of PFOA or PFOS and allow government officials to evaluate and undertake timely response actions, if appropriate to do so. To ensure that it focuses its resources on those releases that threaten public health or welfare or the environment, EPA, may, however, consider adjusting the default RQ in the future if it receives data regarding the scope of releases of PFOA or PFOS indicating that one pound is not a suitable unit on which to base a notification requirement.

b. The Reportable Quantity (RQ) of One Pound Is Appropriate

Comment: A few commenters expressed support for a RQ of one pound.

Response: For the reasons provided in response to the prior comment (*see 1.a.),* the Agency agrees that it is appropriate to maintain a reportable quantity of one pound over a 24-hour period.

c. The Reportable Quantities (RQs) Should Be Chemical-Specific, Not Applied to PFAS as a Class

Comment: One commenter argued that EPA's decision to establish a RQ of one pound is indicative of the fact that the Agency lacks sufficient risk information for PFOA and PFOS to set a chemical-specific RQ, thereby demonstrating that the rulemaking is premature. Another commenter stated that there is precedent for tailoring reportable quantities to the unique characteristics of a given class of hazardous substances; specifically, the commenter pointed to the RQ approach the Agency has adopted with respect to radionuclides as support for their proposed methodology.

Response: This action is focused on designating PFOA and PFOS, and their salts and isomers as CERCLA hazardous substances. CERCLA 102(b) establishes a default of one pound and EPA has assigned 1 pound for each of these substances, including their salts and isomers. The Agency may revise the RQ in the future through notice and comment rulemaking after reviewing release information received pursuant to CERCLA 103.

On May 25, 1983, the Agency proposed to adjust the statutory default

[69] Reference Dose (RfD)—An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments. Generally used in EPA's noncancer health assessments. Durations include acute, short-term, subchronic, and chronic. (*https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system*).

RQ of one pound for radionuclides. *See Notification Requirements; Reportable Quantity Adjustments,* 48 FR 23514, 23552 (May 25, 1983). EPA subsequently published a final rule and assigned a specific RQ for each radionuclide based on a methodology specific to those substances. *See Reportable Quantity Adjustment Radionuclides,* 54 FR 22405, 22524 (May 24, 1989). Similarly, with respect to PFOS and PFOA, the Agency may exercise its discretion at any time after designation to adjust the RQ if it determines that the circumstances warrant doing so.

d. Effluent That Violates NPDES Permit Limits

Comment: One commenter stated that effluent that violates any present or future NPDES permit covering PFAS needs to be reported under CERCLA to help attain the primary goal of this rulemaking: determining where releases of PFOA and PFOS occur and in what amount.

Response: Whether a particular release of PFOA or PFOS is exempt from CERCLA reporting requirements requires a case-by-case evaluation based on specific permit language or applicable control requirements. Generally, any release that violates a standard or limit specified in a facility's NPDES permit must be reported pursuant to CERCLA section 103 and EPCRA section 304. If the permit limit is below the RQ for these substances, those releases are not required to be reported.

d. The Reportable Quantity (RQ) Should Be Applied Over a Different Time Period Than 24 Hours

Comment: One commenter argued that EPA should require reporting of releases on a monthly basis rather than over a 24-hour period. To support this proposition, the commenter argued that the conditions of water-borne discharges do not change on a day-to-day basis and reporting can therefore be handled through other statutory reporting structures, specifically, under the terms of NPDES permits issued under the CWA. The commenter also argued that this designation would result in inconsistent reporting requirements as between TSCA and CERCLA. Here, the commenter stated that, under EPA's Chemical Data Reporting (CDR) rule, PFOA and PFOS are subject to a 2,500-pound reporting threshold at a single site. The commenter then noted that, regardless of TSCA stipulations, if the reporting quantity threshold is one pound in 24 hours, a site could spill 0.99 pounds per day for 365 days a year, or nearly 360 pounds, with no reporting required. If, however, EPA imposed a weekly or monthly RQ reporting timeframe, the commenter contended that this issue would be addressed. Finally, the commenter noted that, pursuant to Toxics Release Inventory reporting requirements, facilities in regulated industry sectors must report annually on releases and the waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (100 pounds for PFOA and PFOS).

Response: EPA declines the commenter's request to amend the timeframe it uses to determine if a reportable release has occurred. The Agency believes that a 24-hour reporting period—which it has utilized successfully for 38 years and with which the regulated community is highly familiar—best serves the primary purpose of CERCLA's notification requirements, namely, to alert government officials to releases that may require timely and proper response action to prevent or mitigate damage to public health or welfare or the environment. To the extent facilities are aware of ongoing releases of hazardous substances below the reportable quantity, the Agency believes that regulated entities will conduct due diligence by reporting any releases that may cause substantial danger to the public health, or welfare or the environment. Finally, while the commenter identifies what it regards as inconsistencies in reporting thresholds between various regulatory programs, EPA notes that statutory and regulatory programs maintain reporting thresholds that are intended for different purposes. For example, EPCRA section 313 (Toxic Release Inventory (TRI)) requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. TRI data can, in conjunction with other information, be used as a starting point in evaluating such exposures and the risks posed by such exposures. The purpose of the Chemical Data Reporting Rule under TSCA is to provide EPA with information on the production and use of chemicals in commerce. However, release reporting requirements under CERCLA section 103 and EPCRA section 304 create a reporting process that inform government officials of releases that require immediate evaluation to determine the need for response action.

f. The Proposal Provides Little or No Guidance on How PFAS Quantities Are To Be Specifically Determined or Calculated for the Purposes of the RQ

Comment: Several commenters argued that the designation would necessitate costly daily sampling for PFOA and PFOS; relatedly, these commenters also claimed that the designation fails to provide adequate guidance regarding the appropriate methodology for sampling of PFOA and PFOS.

Response: This final designation under CERCLA does not require any testing and EPA does not intend to require any further testing beyond that which is already required by other statutes and their implementing regulations. Testing may be required on a site-specific basis, consistent with CERCLA section 104(b).

g. Reportable Quantities of PFAS May Be Difficult or Impossible To Identify Due to Being Proprietary, Being Disclosed Incompletely in Safety Data Sheets, or Not Meeting the 1 Percent Labeling Threshold

Comment: Several commenters were concerned with the identification of reportable PFAS because in some cases, PFAS chemicals in products are listed as proprietary, not by name or Chemical Abstracts Service (CAS) number. Furthermore, because not all Safety Data Sheets (SDSs) accurately disclose PFAS constituents, these commenters argue that the designation will result in constant uncertainties regarding quantities, reporting and recordkeeping, even though EPA has taken the position that SDSs and Technical Data Sheets should be considered primary sources of information in ascertaining the presence of PFAS-containing compounds. One commenter also noted that compositions of products containing PFOS or PFOA, or other PFAS, are currently not required to be communicated on Safety Data Sheets or otherwise labeled normally below one percent, questioning how EPA proposes to make determinations on volumes if percent composition is not disclosed by manufacturers. One commenter stated that the rule should clarify expectations and requirements for PFOA and/or PFOS producers regarding the communication and/or disclosure of these substances when used as ingredients. By way of example, the commenter suggested that EPA should consider whether PFOA and PFOS producer reporting requirements should be effectuated through OSHA regulations such as the Hazard Communication Standard.

One commenter noted that EPA's current proposal would designate not just PFOA and PFOS as hazardous substances with RQ requirements, but also ''their salts and structural isomers'' which often do not even have their own names. The commenter asserted that if a constituent has not even been named yet and/or is not currently detectable with the available sampling methods, then the regulation of that constituent is not practicably enforceable and puts regulated entities in an untenable situation.

Response: According to OSHA's Hazard Communication Standard (HCS), a manufacturer, importer, or employer may claim ingredients in their product as proprietary if they meet the requirements of 29 CFR 1910.1200(i). However, if a chemical ingredient is below the thresholds (*i.e.,* 1% or 0.1%, depending on the specific health endpoint), it is required to be listed on an SDS if the chemical can cause a health hazard below the cut-offs.[70] Downstream users of mixtures or products that contain PFOA, PFOS, or their salts and isomers are encouraged to contact their distributors as well as manufacturers to obtain (SDSs), which should include concentrations of each ingredient or constituent in a mixture or product. The specific requirements for developing SDS and its contents are regulated under OSHA HCS. *See 29 CFR 1910.1200. (Note: EPA's CompTox Chemicals Dashboard (https://comptox.epa.gov/dashboard/) is a resource that can be used to identify salts and structural isomers of PFOA and PFOS. EPA periodically updates the CompTox Chemicals Dashboard to include new information on PFAS, including PFOA and PFOS.)* EPA has amended Table 302.4 of 40 CFR part 302 to designate PFOA, PFOS and their salts and structural isomers and parties that use such chemicals are responsible for knowing the makeup of their products and ingredients and ensuring compliance with the CERCLA and EPCRA reporting requirements if a release occurs. The regulations at 40 CFR 302.6 (b) provides requirements for release reporting of mixtures with known and unknown constituents or their quantities. *https://www.ecfr.gov/current/title-40/chapter-I/subchapter-J/part-302/section-302.6.*

[70] EPA coordinated with OSHA to develop this response.

h. EPA Should Clarify That Any NPDES Permit Violation for PFOA and PFOS Would Not Constitute a ''Federally Permitted Release'' and Must Be Reported

Comment: One commenter argued that EPA should clarify that any releases of PFOA or PFOS in violation of the terms of a NPDES permit would not constitute a ''federally permitted release'' under CERCLA section 101(10)(C) and must therefore be reported in accordance with CERCLA section 103. This commenter also argued that EPA's ability to require monitoring of PFOA and PFOS through NPDES permits is limited because the Agency's April 2022 guidance—*Addressing PFAS Discharges in National Pollutant Discharge Elimination System Permits and Through the Pretreatment Program and Monitoring Programs* (Memorandum)—is directed only at federally issued NPDES permits.

Response: CERCLA requires a person in charge of a vessel or a facility to report any release (other than a federally permitted release) of a hazardous substance over a certain quantity to the National Response Center as soon as they are aware of a release. *See* 42 U.S.C. 9603(a). CERCLA section 101(10) defines the term ''federally permitted release,'' which includes NPDES permits issued under the Clean Water Act. See CERCLA 101(10)(A), (B), & (C). Whether a particular release is a ''federally permitted release'' such that it would be exempt from CERCLA section 103 reporting requirements requires a case-by-case determination based on the specific permit language or applicable control requirement. These provisions are sufficient to inform whether a release is a federally permitted release for any hazardous substance, including releases of PFOA and PFOS. EPA also notes that on December 5, 2022, it updated the Memorandum to provide guidance to States for addressing PFAS discharges when they are authorized to administer the NPDES permitting program and/or pretreatment program. *https://www.epa.gov/system/files/documents/2022-12/NPDES_PFAS_State%20Memo_December_2022.pdf.*

i. Default Reportable Quantity (RQ) of 1 Pound

Comment: One commenter noted that EPA arbitrarily set the default reporting requirement at one pound, which is not supported by scientific analysis.

Response: Although one commenter argues that EPA acted ''arbitrarily'' in setting the reportable quantity (RQ) for PFOA and PFOS at one pound, in fact, the Agency is setting the RQ by operation of law at the statutory default of one pound pursuant to CERCLA section 102(b). *See* 42 U.S.C. 9602(b) (''Unless and until superseded by regulations establishing a reportable quantity under subsection (a) of this section for any hazardous substance as defined in section 9601(14) of this title, (1) a quantity of one pound, or (2) for those hazardous substances for which reportable quantities have been established pursuant to section 1321(b)(4) of title 33, such reportable quantity, shall be deemed that quantity, the release of which requires notification . . .'').

2. Community Notification Requirement Under CERCLA Section 111(g)

Comment: One commenter requested clarification regarding the impact of the rule on the community notification requirement of section 111(g) of CERCLA.

Response: Upon finalization of this rulemaking, the owner or operator of a facility or vessel from which PFOA or PFOS have been released will be required to ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area.'' CERCLA section 111(g). Note that the section 111(g) notification mechanism is independent of the reporting requirements of section 103(a). See Notification Requirements; Reportable Quantity Adjustments, 50 FR 13456, 13464 (Apr. 4, 1985) (''One commenter asked whether RQ notification requirements revoke section 111(g). The newspaper notification requirement established by section 111(g) of CERCLA is not affected by any of the notification requirements in today's rule.'').

E. National Priorities List (NPL) Sites—Existing and Future Contamination

Comment: A number of commenters were concerned that the designation of PFOA and PFOS would result in the addition of a significant number of new sites to the NPL, thereby preventing EPA from focusing on significantly contaminated sites. One commenter noted that designation would require EPA to prioritize the cleanup of new Superfund sites, but also claimed that the Agency has not clarified how any prioritization process would occur. Another commenter noted their specific concern that the designation will result in the implication of a significant number of agricultural operations as Superfund sites.

Several commenters also argued that designation could both extend the

remediation timeline for existing Superfund sites and slow down the rate at which sites can be deemed ''closed.'' Ongoing and unmitigated releases could result in a contaminated site having to be cleaned up multiple times. Finally, multiple commenters stated that EPA has not properly accounted for and considered the additional economic burden associated with the addition of multiple new Superfund sites, reopening of sites, and corresponding cleanup obligations.

Response: EPA does not expect the number of sites on the NPL to substantially increase after designation. EPA already has the authority to list PFOA and PFOS sites to the NPL, and the rule has no impact on that authority. Indeed, EPA has already listed sites on the NPL in part due to the presence of these substances at a site, and this practice would continue. For example, Saint-Gobain Performance Plastics, Blades Groundwater, and Galey and Lord mention PFOA, PFOS, or both PFOA and PFOS, in their listing proposal. Designation does not automatically make sites eligible for placement on the NPL because of the presence of PFOA and PFOS.

Designation does not change the Hazard Ranking System (HRS), which is EPA's primary tool for evaluating releases to determine NPL eligibility. (40 CFR part 300, Appendix A). The HRS broadly defines ''hazardous substance'' as including CERCLA hazardous substances, pollutants, and contaminants as defined in CERCLA section 101(14) and 101(33). Available scientific data demonstrate that PFOA and PFOS meet the definition of pollutant or contaminant, and therefore sites with PFOA and PFOS are evaluated in the NPL listing process, regardless of designation.

The HRS process considers several factors for the purpose of scoring a site and determining its eligibility for listing on the NPL. The HRS is designed to assesses the relative potential of sites to pose a threat to human health or the environment. Scores are based on three categories, including the likelihood that a site has released or has the potential to release hazardous substances and/or pollutants or contaminants into the environment; characteristics of the waste (toxicity and waste quantity); and people or sensitive environments (targets) affected by the release. These scores are calculated for one or more pathways including ground water migration, surface water migration, soil exposure and subsurface intrusion, and air migration. If the combined scores meet or exceed the threshold listing score of 28.5, the site is eligible for the NPL.

Even when a site is eligible for the NPL, EPA may choose to not list the site and look to other options. Alternatives to NPL listing may include the Superfund Alternative Approach, State cleanup, cleanup by other Federal agencies, EPA removal action, deferral to another EPA program, or various other enforcement mechanisms. Thus, PFOA or PFOS releases may be addressed through non-NPL mechanisms even after designation.

Between FY 2003 and FY 2022, only about four percent of all contaminated sites added to EPA's Active Site Inventory were placed on the NPL. Since 2013, EPA has, on average, added 11 non-federal sites per year to the NPL,[71] and EPA does not expect the rate at which annual additions to the NPL occur to increase as a result of this rule. Moreover, NPL listing does not trigger any immediate actions, liability, or requirements for the site.[72]

A hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response actions. Response actions, which include investigations of releases of hazardous substances and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific. EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment; and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach.

EPA disagrees with the commenter that designation of PFOA and PFOS will slow the Agency's ability to remediate Superfund sites. Designation itself does not affect the length of time it may take to fully implement a remedial action. However, in some cases, there may need to be additional work to address PFOA and PFOS contamination, depending on what other contaminants of concern (COCs) are located at a site and whether the responses to those other contaminants have the co-benefit of addressing PFOA and PFOS contamination. Typically, remedial actions address a number of COCs at once. In some cases, the remedy for other COCs will also address PFOA and PFOS contamination; in other cases, additional work will be needed. For instance, if PFOA and PFOS are not part of a remedy for the site, adding them to the remedy would then have the potential to increase efforts and cost of the remedy (*e.g.,* by increasing the frequency of GAC replacement).

In all cases, EPA should evaluate whether the remedy can mitigate any unacceptable risk from PFOA or PFOS contamination or whether additional actions may need to be taken. CERCLA section 121 provides that if an action is needed to assure protectiveness as a result of findings of a five-year review, those actions can be taken. In some cases, it may be necessary to revise or expand the previous risk assessment as part of a five-year review. For example, the risk assessment may need to be revised when there is a new exposure pathway, a new potential contaminant of concern, or an unanticipated toxic byproduct of the remedy. Five-year reviews (FYR) can also recommend further investigation to determine whether an additional response action is needed. *See* CERCLA section 121(c); 40 CFR 300.430(f)(4)(ii).

Additionally, several commenters stated that without first ensuring PFOA and PFOS are no longer entering the environment, ongoing and unmitigated releases could potentially cause a site to be cleaned up multiple times. First, PFOA and PFOS contamination stems largely from historic releases. Even though there will likely be future releases, the use of PFOA and PFOS has diminished, and EPA does not expect releases at particular sites to result in additional widespread, significant contamination at or from that site, in part because the designation will allow EPA to act earlier. Second, EPA notes that (as discussed in Section III.C.), it has committed to a comprehensive and

[71] This estimate is based on data from EPA's SEMS database with respect to non-federal NPL sites. EPA determined that it was appropriate to assess the designation's impact with respect to non-federal NPL sites only, because federal sites are generally expected to address PFOA and PFOS in the absence of designation consistent with CERCLA section 104. As discussed in Chapter 2 of the RIA, federal sites are addressing PFAS in the baseline as authorized by CERCLA section 104 and corresponding Executive Orders, as required by the NDAA, and consistent with federal facilities agreements under CERCLA section 102. Therefore, EPA expects that federal sites will address PFOA and PFOS contamination in the absence of the final rule. With federal sites taking action to address PFAS in the baseline, indirect impacts of the final rule will likely be related to actions taken at non-federal sites. For additional context, since FY 2000 EPA has added 8 federal sites to the NPL.

[72] EPA considered the portion of non-federal NPL sites that may be impacted by designation depending on site-specific circumstances. Of final, proposed, or deleted non-federal NPL sites that have been tested for PFOA and/or PFOS, an estimated 33.1% of NPL sites have detectable levels of PFOA and/or PFOS. See Section 3.3 of the RIA for more details about this estimate. In evaluating the designation's impact on non-federal NPL sites, this estimate is instructive and serves as a benchmark for assessing designation's potential impact to those sites. There are currently 5 sites where either PFOA or PFOS contributed to NPL listing.

ambitious whole-of-Agency plan to address PFAS. Under this approach, EPA has identified a variety of authorities, including TSCA, SDWA, and RCRA, that it intends to use to prevent or minimize ongoing PFOA and PFOS releases into the environment. Additionally, EPA has considered the economic impacts of designation, including a consideration of potential impacts of designation on the NPL listing process. Please see chapter 5 of the RIA for this final rule.

F. Regulate PFAS as a Class

Comment: A few commenters stated that EPA should regulate PFAS as a class rather than listing chemicals one by one.

Response: PFOA and PFOS are prevalent because they have been produced and used since the 1940s, were among the most widely used of the PFAS constituents and persist in the environment for a substantial period of time. EPA considered the available scientific and technical information, and concluded each of these substances may present substantial danger to public health or welfare of the environment. EPA also evaluated the totality of the circumstances, including available scientific and technical information, and concluded that designation is warranted. The Agency also recently sought input and data regarding potential future hazardous substance designation of categories of PFAS and is still evaluating the feedback it received on this issue. See Addressing PFAS in the Environment, 88 FR 22399 (Apr. 13, 2023).

G. Phase-Out & PFOA Stewardship Program

Comment: Several commenters also argued that the production of PFOA and PFOS is being phased out, thus the value of this rulemaking is questionable.

Response: EPA disagrees with the commenter's assertion that the value of designating PFOA and PFOS is questionable since these chemicals have been phased out in many cases. First, although PFOA is not produced domestically by the companies participating in the 2010/2015 PFOA Stewardship Program, PFOA may still be produced domestically by non-participating companies. PFOS may still be produced or used domestically as well. Second, EPA has also published Significant New Use Rules (SNURs) to require notification to EPA before manufacture (including import) of certain PFAS, including PFOA and PFOS. This notification process would allow EPA the opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity. However, these SNURs exempted certain ongoing uses, including a few specifically limited, highly technical uses. In the absence of any notices received under these SNURs, EPA has limited sources of data regarding the ongoing use of PFOA and PFOS. Currently, the CDR generally requires manufacturers (including importers) to report for PFOA and PFOS if they meet a 2,500-pound production volume threshold at a single site. TRI reporting requires facilities to report releases of PFOA and PFOS if the facility manufacture, produce, or otherwise use at or above 100 pounds per year. Recent TRI reports indicate there maybe on-going uses of these substances. While TRI reports show on-going uses, EPA is unable to definitively state the extent to which PFOA and PFOS are still in commerce in the United States.[73]

Regardless of the phase-out, designation is warranted based on the scientific and technical data available, suggesting that releases into the environment pose a hazard; are persistent and mobile (fate and transport); and prevalent in the environment. EPA has existing data that suggest that, despite the phase-out, PFOA and PFOS will continue to be detected in the environment. For example, EPA has detected PFOA and PFOS at approximately 400 NPL sites. These sites are mainly locations associated with AFFF use, textile coating operations, metal plating facilities, and landfills. As appropriate, these sites, and others like them, should be investigated, and site-specific risk assessments should be performed to assess whether further response actions, if any, are necessary to protect human health and the environment. Designation will allow EPA to address the legacy of sites that are contaminated with these substances and address future releases.

H. Managing PFOA and PFOS Contaminated Waste

Comment: Several commenters claimed that the designation of PFOA and PFOS will result in a significant increase in the generation of hazardous wastes; these commenters also argued that EPA has not provided sufficient disposal capacity or storage requirement guidance to address the ramifications of the designation. Multiple commenters also stated that the Agency may not be able to satisfy the requirements of CERCLA section 104(c)(9), which requires States to assure the availability of hazardous waste treatment or disposal facilities that have adequate capacity to manage the hazardous waste reasonably expected to be generated within the State over 20 years, prior to EPA providing funding for any remedial actions. Relatedly, some commenters noted that EPA has not disclosed whether it has entered into any agreements with States to ensure that they possess the capacity to destroy, treat, or securely dispose of material contaminated with PFOA and PFOS. Further, several commenters argued that EPA has not considered whether Subtitle C landfill capacity is available to accommodate PFOA or PFOS-contaminated hazardous waste. Some commenters also alleged that EPA has not described disposal methods for contaminated soils or other media from new Superfund sites that could be created in the wake of this rulemaking. Finally, several commenters argued that EPA must finalize its *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Materials Containing PFAS-Substances* (''Interim Guidance'') and estimate available waste disposal capacity before finalizing this rulemaking.

Response: Comments suggest a misunderstanding of waste disposal requirements under CERCLA. The Agency disagrees with the assumption that all waste containing PFOA and PFOS must be disposed of in Subtitle C facilities. EPA's *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024)*, acknowledges that PFAS wastes could be sent to both hazardous waste and municipal solid waste landfills. For CERCLA cleanups, section 121(d)(3) of CERCLA, as implemented by 40 CFR 300.440 (''*Offsite Rule*''), applies to any CERCLA response action involving the off-site transfer of any hazardous substance or pollutant or contaminant (*CERCLA wastes*). The Offsite Rule requires that CERCLA wastes are transferred to a facility operating in compliance with applicable Federal and State requirements for the waste at issue. As such, for CERCLA cleanups, only hazardous wastes listed or identified under RCRA section 3001 (or an authorized State program) are required to be managed at RCRA Subtitle C facilities.

EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA

[73] The Agency expects to receive additional information about ongoing use of PFAS as part of the TSCA section 8(a)(7) PFAS reporting rule that was finalized on October 11, 2023 (88 FR 70516).

and PFOS contaminated materials. EPA also acknowledges that CERCLA section 104(c)(9) does not allow the Agency to provide any remedial action funding to a State, unless the State first enters into a Superfund State Contract or Cooperative Agreement (CA) that assures the availability of adequate capacity to manage hazardous wastes generated in the State for 20 years following the date of the response agreement. EPA is designating PFOA and PFOS as CERCLA hazardous substances. No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA,[74] However, PFOA- and PFOS-containing waste is and will likely continue to consume a fraction of hazardous waste treatment and disposal capacity. Although waste containing PFOA and PFOS is not necessarily hazardous waste (unless the particular wastes are hazardous for some other reason), some waste generators, perhaps to be cautious, have been sending PFAS-containing wastes to hazardous waste facilities. To ensure hazardous waste landfill capacity is available in the future, EPA reviews and analyzes the Biennial Hazardous Waste Report and other data to develop and then publish an assessment of national capacity for hazardous waste management. The last such capacity assessment indicated that there is adequate capacity nationwide through 2044, and it would have incorporated PFOA and PFOS as wastes in the category of ''Not RCRA Federally-Defined Hazardous Wastes.'' Of these wastes, no assumption regarding a certain percentage of PFOA and PFOS was made. Anew assessment is currently underway to incorporate new information and extend the time horizon.[75] EPA will continue to work with States to monitor waste treatment and disposal capacity and report on the status.

The science on treating, destroying, and disposing of PFAS is evolving. The National Defense Authorization Act for Fiscal Year 2020 (FY 2020 NDAA) directed the Agency to publish interim guidance on the destruction and disposal of PFAS and materials containing PFAS. Subsequently, on December 18, 2020, EPA developed and issued the *Interim Guidance* (*U.S. EPA, 2020*), which outlines the current state of science on techniques and treatments that may be used to destroy or dispose of PFAS and PFAS-containing materials from non-consumer products. Consistent with the FY 2020 NDAA, EPA is also required to publish revisions to the interim guidance as appropriate, but not less frequently than once every three years. EPA recently posted *the Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances—Version 2 (2024*).

I. Comments on Economic Assessment/ Regulatory Impact Analysis

Comment: Several commenters asserted that EPA must prepare and publicly issue a full economic analysis of the rulemaking. These commenters claimed that EPA's economic assessment is insufficient for failing to provide any quantitative assessment of anticipated indirect costs, particularly those related to increased response actions. Several commenters called upon the Agency to issue a complete RIA while other commenters stated that EPA is required to prepare a regulatory cost benefit analysis consistent with Executive Order 12866. These commenters also asserted that EPA should conduct a full RIA pursuant to OMB Circular A–4 that considers the full compliance and cleanup costs, including the direct and indirect costs and benefits, associated with the designation. One commenter stated that the rulemaking cost estimates prepared by EPA do not appropriately reflect the total costs associated with the designation.

Response: With new information received during the public comment period, EPA updated its analysis of direct costs. As part of this rulemaking, EPA has expanded its economic assessment and has conducted an RIA consistent with E.O. 12866 and OMB Circular A–4 in support of designation. As required by the E.O. and Circular A–4, the RIA assesses reasonably foreseeable indirect costs, transfers, and benefits. Specifically, for costs, transfers and benefits, EPA has developed estimates under a range of scenarios based on historic information about response costs and benefits. These ranges reflect the uncertainty associated with estimating potential response costs, transfers, and benefits, as it is difficult to assess with certainty what future actions will be taken since CERCLA decisions are made on a site-specific basis. EPA also asserts that the scope of costs counted by the Agency as direct costs—including an estimated low and high range of potential notification requirement frequencies and associated costs—is consistent with the requirements of E.O. 12866 and OMB Circular A–4. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts. Please see chapters 3, 4, and 5 of the RIA for more information about EPA's methodologies and discussion of direct and indirect costs, benefits, and transfers.

1. Liability and Costs to Public Utilities

Comment: Numerous comments claim that EPA has failed to consider the potential impact of the designation on public water utilities/water systems and ratepayers with respect to potential litigation costs. These comments also argue that the designation does not account for the potential remediation costs associated with PFOA and PFOS cleanups (which the commenters assert could be passed on to local communities and public clean water utility ratepayers). These commenters also claim that local drinking water and wastewater agencies will incur substantial costs to remove PFOA and/or PFOS from water sources and propose that all such direct and indirect costs should be evaluated in a full RIA. One commenter asserted that EPA's approach to designation could potentially harm sectors and facilities that provide essential daily functions to communities, such as wastewater treatment facilities and municipal landfills (*i.e.,* facilities that do not generate or use PFAS but that may, in the regular course of business, receive waste or wastewater containing PFAS).

Response: The Agency recognizes that certain stakeholders are concerned about CERCLA liability resulting from the designation of PFOA and PFOS as hazardous substances. The most significant direct impact of this CERCLA designation is the requirement that any person in charge of a vessel or facility report a release of PFOA and/or PFOS of one pound or more within a 24-hour period. Neither a release nor a report of a release automatically triggers cleanup action under CERCLA. EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. In

[74] EPA has proposed to amend its RCRA regulations to add multiple PFAS compounds, including PFOA and PFOS, as hazardous constituents. These PFAS would be added to the list of substances identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the corrective action process at hazardous waste treatment, storage and disposal facilities. Although this is one step toward listing a hazardous waste, it is not a regulatory hazardous waste listing.

[75] Background information and links to related documents are available at *https://www.epa.gov/hwpermitting/assessment-national-capacity-hazardous-waste-management.*

addition, designation does not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Likewise, CERCLA affords the EPA broad discretion as to whether or how to respond to a release. For those reasons, EPA cannot assess with reasonable certainty what liability outcomes may indirectly result from this designation since those outcomes are often linked to EPA's discretionary decisions with respect to CERCLA response actions as well as site-specific and fact-dependent court rulings. Nevertheless, EPA considered these issues in its totality of the circumstances analysis. For further information regarding the interplay between the designation and potential liability concerns please see sections VI.B.2 and VI.B.3.

Efforts to address PFAS in public drinking water and wastewater treatment have already been initiated prior to this designation, and the associated costs of those efforts are attributable to those separate efforts. In the case of drinking water utilities, EPA's 2024 NPDWR mandates that certain drinking water utilities (community water systems and nontransient, noncommunity water systems) should deliver drinking water with PFOA and PFOS concentrations below the MCLs. The costs of monitoring, treatment, administration, disposal of drinking water treatment media residuals, and other costs have been considered in the associated Economic Analysis as part of that rulemaking effort. *Please see 2024 NPDWR. https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas,* or visit *www.regulations.gov,* Docket No. EPA–HQ–OW–2022–0114. For potential cleanups of private drinking water wells, EPA acknowledges it has expanded its economic assessment to estimate a subset of potential health benefits where data was available to allow quantification. This subset includes those populations who rely on private drinking water wells within one mile of sites that may have response and cleanup as a result of the final rule. Refer to RIA Chapter V.

2. Consideration of Costs for Small Entities

Comment: One commenter expressed concern that the designation may create significant costs for small entities associated with monitoring and analyzing samples for PFOA and PFOS to ensure compliance with CERCLA. The commenter recommended EPA evaluate and consider the real costs associated with the designation through an evaluation of the number and types of facilities that may release reportable quantities of PFOA or PFOS, to determine what monitoring and analysis costs these facilities may incur to ensure compliance with CERCLA. Then, the commenter suggested that if EPA determines that costs should not be considered as part of the designation, costs should be considered as a factor of complying with CERCLA.

Response: EPA disagrees with the commenter that designation of PFOA and PFOS as CERCLA hazardous substances will lead to significant cost impacts for small businesses. First, this rule does not require monitoring and analysis specifically. Second, in its RIA, EPA demonstrated that the rule would not result in a significant impact to a substantial number of small entities; in fact, consistent with long-standing EPA policy regarding the implementation of the Regulatory Flexibility Act, the RIA considered small entity impacts related to the direct cost impacts of the rule and found that they are limited to the costs associated with the reporting of PFOA/PFOS releases at or above the RQ.

3. Direct Costs for Rule Familiarization

Comment: One commenter stated that EPA failed to consider the cost of ''regulatory familiarization'' in its economic analysis of the rulemaking. The commenter described ''regulatory familiarization costs'' as accounting for the value of time and effort that every potentially affected individual or business must undertake to determine if a regulation applies to their situation or not, and how their activities must adapt to comply.

Response: Rule familiarization constitutes a negligible cost of the rule. Facilities are expected to be familiar with the baseline requirements associated with reporting releases of non-PFOA/PFOS CERCLA hazardous substances to the NRC and to the State, Tribal and local emergency planning and response agencies. While the final rule is adding PFOA and PFOS to CERCLA's list of hazardous substances, this designation does not change or add requirements to CERCLA section 103, CERCLA section 111, and EPCRA section 304 release notification requirements.

4. Costs, Benefits, and the Economic Assessment

Comment: One commenter states that the rulemaking will result in a net social cost as markets over-adjust to concerns regarding CERCLA's joint and several liability scheme. The commenter also contends that any transfer of costs from the public to polluters could occur even in the absence of the designation, thereby concluding that the rulemaking is unnecessary. Finally, the commenter states that any consistency between the designation and ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination as to whether the designation meets a compelling public need.

Response: EPA disagrees with the commenter that the designation will cause the market to over-adjust in response to CERCLA's liability provisions. Market efficiency generally increases as more information becomes available. EPA is unaware of data suggesting that an over-adjustment is likely, and the commenter provided no such data. Further, once CERCLA's notification requirements and broadened enforcement authorities are applicable to PFOA and PFOS releases, the likelihood that costs will be shifted from the Federal government to polluters will increase. Specifically, reporting will facilitate increased transparency regarding releases of PFOA and PFOS, which will, in turn, both inform the Agency's understanding of the presence of these substances in the environment and allow EPA to respond to contamination in a timely manner.

EPA disagrees with the commenter that the consistency between the designation and other ongoing actions to address PFOA and PFOS contamination is irrelevant to a determination that the rule meets a compelling public need. Designation is still warranted independent of other Agency actions and is consistent with EPA's Agency-wide approach outlined in the Roadmap. As noted by the commenter, OMB Circular A–4 states that an agency ''should try to explain whether the action is intended . . . to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy.'' Greater consistency between actions will ''improve governmental processes'' by allowing for greater efficiency and effectiveness in addressing PFOA and PFOS contamination across the United States. Additionally, when EPA is able to transfer certain response costs to PRPs, this represents an improvement in societal equity.

Comment: One commenter argues that EPA has not explained how designation encourages better waste management practices or how PFOA or PFOS-contaminated materials should be disposed of. This commenter also argues that EPA has failed to support its assertion that the designation will

produce public health benefits. Here, the commenter points out that EPA identifies the regulatory requirement to report a release of one pound of PFOA or PFOS as a particular benefit of the proposed rulemaking but contends that the quantity of material that would need to be released for reporting requirements to attach would be significant. Finally, the commenter states that the designation may have the unintended consequence of increasing treatment costs in both drinking water and wastewater.

Response: EPA agrees with the commenters that reports of releases at or above the RQ represent a meaningful benefit of the rule, as reporting will allow EPA to evaluate and respond to such releases in a timely manner. EPA disagrees with the commenter that the rule will not lead to improvements in the management of PFOA and PFOS contaminated materials. A potential direct benefit that may result from the reporting requirement is better waste management and/or treatment by facilities handling PFOA or PFOS, resulting from improved efforts to further reduce potential releases. Greater transparency provided by release reporting can lead to fewer releases to the environment and thus to potential health benefits associated with avoided exposure. For additional information regarding the potential benefits of the designation, including other benefits of release reporting, see Section VI of this preamble.

In this final action, EPA has expanded its economic assessment of indirect benefits to include illustrative quantified and unquantified health benefits. EPA quantified a small subset of potential health benefits. This includes an illustrative assessment of reduced incidence of cardiovascular disease, birthweight impacts, and renal cell carcinoma under a range of scenarios. This considers potential benefits to those populations which rely on private drinking wells, where there may be response and cleanup as a result of the final rule. Additionally, EPA assessed additional unquantified health benefits. *See* RIA Chapter 5.

EPA does not agree with the commenter that the proposed rule will hinder water treatment or efforts to remove background levels of PFOA or PFOS in wastewater and drinking water. When, how, and why the water sector would remove these substances from drinking water and whether they dispose of it in a hazardous waste landfill is complex and will depend on the volume and concentration of PFAS captured, availability of disposal sites, decisions made at individual public water systems, and State and Federal regulatory actions and enforcement actions.

EPA also disagrees with the claim that designation will increase the costs associated with managing drinking water treatment residuals. As discussed in section VII.I.1, efforts to address PFAS in drinking water and wastewater treatment have already been initiated prior to this designation, and the associated costs of those efforts are attributable to those separate efforts. The NPDWR Economic Assessment Appendix H includes a sensitivity analysis that accounts for potential cost increases associated with treatment of residuals as hazardous waste. The designation of PFOA/PFOS as CERCLA hazardous substances does not require disposal or treatment of water treatment residuals as hazardous waste.

Comment: One commenter challenged whether the designation would have the benefits that EPA claims. The commenter asserts that existing tools at EPA's disposal, as well as those in development, can provide the Agency with the authority it needs to address PFOA and PFOS releases and obviate the need for designation. The commenter also states that EPA's failure to quantify the likely costs and purported benefits of this rule are especially egregious in light of the Agency's alleged failed to consider alternative actions to achieve its goals. The commenter also encouraged EPA to conduct a full RIA. Finally, the commenter claimed that there are negligible positive effects associated with the designation, and challenged EPA's assertion that substantial benefits will flow from the designation as flawed.

Response: EPA disagrees with the commenter that the rule is unlikely to lead to the benefits the Agency has identified. EPA has identified a significant body of scientific evidence demonstrating that PFOA and PFOS are persistent and mobile in the environment, and that exposure to PFOA and PFOS may lead to adverse human health effects. Therefore, to the extent that this designation results in reduced or eliminated exposure to PFOA/PFOS, as EPA expects it will, there may be potentially significant human health benefits associated with designation. EPA further explains its reasoning regarding these benefits in Section VI.A of this preamble and in the RIA. For example, the notification requirement under the designation will facilitate earlier notification of EPA and State authorities regarding releases of PFOS and PFOA. Relatedly, designation will enable EPA to exercise its statutory authorities to address PFOA and PFOS contamination in a timely manner.

With respect to the commenter's claims that the Agency has failed to substantiate its quantification of potential costs, transfers, and benefits, the RIA accompanying the final rule has quantitatively assessed such impacts to the extent possible. Additional benefits and costs remain unquantified due to a lack of available data and highly uncertain circumstances, as further discussed in the rule and RIA. Additionally, EPA has included an analysis of potential alternative policy options associated with the reporting requirement; details of this analysis are found in the Appendix of the RIA.

a. Indirect Costs

Comment: One commenter points out that EPA's economic assessment estimates only the costs associated with reporting activity. The commenter also stated that all costs related to potential increases in response activities and increases in the speed of response activities are only qualitatively described, and that EPA refers to these costs as indirect costs. However, when EPA discusses the benefits of the proposed rule, all the reported benefits related to health protection stem from these ''indirect'' effects. The commenter also said that costs associated with conducting response activities, including the significant costs associated with complex litigation that frequently occurs under CERCLA, is a direct impact of designating substances as CERCLA hazardous substances and must be considered in a regulatory impact analysis. EPA has a wealth of information to inform the frequency at which sites are placed on the NPL; data also exist to inform the costs of final cleanup decisions, as memorialized in public Superfund decision documents. The commenter asserts that while these analyses may not be perfect, they would be far superior to simply ignoring costs which are an inevitable and direct result of the proposed rule.

A commenter asserts that EPA has not fully considered the potential cost impacts of the Proposed Designation and it is evidenced by the lack of information provided by EPA as to the magnitude and scope of those impacts. The commenter states that the limited economic analyses that EPA performed to support the proposal is flawed and its analysis about airports is particularly deficient. The commenter states that the airport analysis simply does not make sense, and seems to have been completed in a vacuum, with little or no outreach to airport operators or others with airport expertise. Another

commenter pointed out that the cost for the airport industry to transition to a new foam is not insignificant and many airports will struggle to transition absent any Federal grant funding.

Response: EPA disagrees with the commenter's assertion that potential response costs are direct; such actions are discretionary, contingent, and made on a site-by-site basis. EPA also disagrees that the Agency ignored the potential indirect costs of the proposed designation of PFOA and PFOS as CERCLA hazardous substances; the economic assessment developed for the proposed rule included a detailed qualitative assessment of these potential indirect costs. The RIA accompanying the Final Rule provides quantified estimates of potential indirect costs and cost transfers associated with response, as well as certain related indirect benefits. These estimates are in part based on the data suggested by the commenter, *e.g.,* NPL listing process, RODs, etc.

EPA does not agree with the commenter that a more detailed evaluation of direct costs is necessary. EPA provides, in the RIA, an estimated low and high range of potential reporting requirement frequencies and associated costs. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts. To better inform the public of potential indirect costs and benefits, EPA has expanded its analyses of indirect costs, cost transfers, and benefits in the final rule RIA relative to the analysis developed for the proposed rule. For many of the potential impacts that could result from the designation, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in response activity.

EPA also considered quantitative and qualitative benefits and costs as part of its totality of the circumstances analysis. Please see Section VI of this preamble.

EPA appreciates the information provided by commenters on potential PFAS cleanup costs at airports regarding the costs to replace AFFF delivery systems. However, EPA disagrees that the designation would lead to a significant increase in costs of transitioning to use of PFAS-free foam for airports. Independent of EPA's CERCLA hazardous substance rulemaking, Congress has taken certain actions to address PFAS contamination, including directing the transition away from PFAS-containing AFFF, protecting fire fighters, preventing runoff from airports, and requiring DOD to prepare a remediation schedule and develop information about associated costs. The aviation industry is already in the process of transitioning away from AFFF to other types of firefighting foam that do not contain PFAS. The costs associated with this transition are unrelated to the proposed designation of PFOA and PFOS as CERCLA hazardous substances. Once this transition is complete and AFFF is no longer used at airports, EPA expects no or minimal releases from airports. In the interim, any direct costs incurred by airports as a result of a designation would be limited to the costs of reporting in the event that a PFOA/PFOS release of one pound or more occurs in a 24-hour period.

Comment: Many commenters disagree with EPA's proposition that the uncertainties are too great to conduct a robust analysis and stated that EPA should conduct a more detailed analysis of the potential direct and indirect effects of the proposed designation. Some commenters asserted that the costs of the designation would dramatically outweigh any benefits. A commenter stated that their analysis, PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites (referred to as the Cleanup Cost Analysis), estimates that the costs of cleanup for potentially responsible parties (PRP) could total over $17.4 billion dollars for existing non-Federal national priority sites alone, and annualized private party cleanup costs at existing non-federal sites could cost $700–$900 million annually. The commenter asserts that despite any existing uncertainties, these costs are simply too large for EPA to ignore. The commenters also pointed to DoD's ongoing remediation work which can provides example cost data that EPA could use to build estimates. EPA has acknowledged cleanup cost uncertainties in the past and has still estimated these costs.

A commenter suggested that EPA should follow OMB guidance and conduct a formal quantitative analysis of relevant uncertainties (*e.g.,* the number of sites to be remediated, the cost of available cleanup technologies, the cleanup level goals for each possible media). Regardless of whether this proposal exceeds the billion-dollar threshold for formal probabilistic uncertainty analysis, Circular A–4 does not prevent an agency from conducting such an analysis if it would inform agency decision making.

Response: EPA has conducted a more thorough and robust RIA that characterizes uncertainties to better describe potential direct and indirect costs, benefits and transfers associated with the designation.

EPA provides, in the RIA, an estimated low and high range of potential reporting requirement frequencies and associated costs. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A–4, this RIA includes an assessment of potential indirect costs, benefits, and transfers to provide the public with insights related to these impacts.

To better inform the public of potential impacts, EPA has expanded its analyses of indirect costs, benefits, and transfers in the final rule RIA relative to the analysis developed for the proposed rule. For costs, transfers, and benefits, EPA has developed estimates under a range of scenarios designed to reflect uncertainty in indirect costs, transfers, and benefits. EPA disagrees that the commenter's cost analysis provides a reasonable representation of the costs associated with the proposed designation of PFOA and PFOS as hazardous substances. The analysis is based on several unfounded or inaccurate assumptions that lead to the overestimation of costs. For example, it assumes that the proposed designation would require all existing non-Federal NPL sites to search for PFOS/PFOA contamination. The designation, however, does not by itself require any systematic re-evaluation of NPL sites. Throughout the Superfund process, from the remedial investigation through site cleanup to five-year reviews, EPA evaluates potential risks posed by actual and threatened releases of hazardous substances, pollutants or contaminants. Since PFOA and PFOS are already considered as pollutants or contaminants, this rulemaking, by itself, should not result in any change to the investigation, cleanup and review processes for sites that are currently on the NPL. Any policy decisions to address PFOA/PFOS subsequent to the hazardous substance designation would likely apply to a subset of NPL sites where potential PFOA/PFOS contamination is not already being addressed rather than systematically to all existing non-federal NPL sites. Chapter 5 of the RIA also presents cost estimates for response at non-NPL sites. As noted in the Final Rule, EPA expects that response costs to address PFOS/PFOA will fall within typical response cost ranges for actions to address other hazardous substances and recognizes that response costs will be significant in some cases.

Additionally, EPA disagrees with the commenter's suggestion for EPA to use cost data for Department of Defense

(DoD) PFAS response efforts as the basis for estimating costs likely to result from the proposed designation. Data for DoD sites (*i.e.,* military installations, facilities of the National Guard, and Formerly Used Defense Sites (FUDS) in the United States) would not be representative of costs associated with non-Federal CERCLA sites as the types, quantity, and handling of PFAS are expected to vary greatly. DoD's cost estimates represent one reference point for potential PFAS response costs with a focus specifically on applications related to national defense. EPA also expects the size and scope of, and therefore costs associated with, Federal PFOA and PFOS cleanup sites to be substantially larger than non-federal sites in part because Federal sites are generally larger in size than non-federal sites. The costs associated with addressing PFAS released by Federal agencies are not representative of non-federal facilities as the types, quantity, and handling of PFAS vary greatly. Among other factors, this may also reflect that AFFF use is disproportionately higher at military sites relative to other sites; AFFF is a major source of PFAS contamination.

J. Enforcement

Comment: Numerous commenters expressed support for the rulemaking, noting that designation facilitates CERCLA's ''polluter-pays'' principle by placing the burden of investigating, responding to, and addressing PFOA/PFOS contamination to the parties responsible for the release. These commenters also stated that designation could potentially accelerate the Superfund cleanup process. One commenter requested that EPA ensure that the costs of cleanup are borne by manufacturers and users of PFOA and PFOS, not the public.

Response: The Agency agrees that designation clearly supports the timely cleanup of contaminated sites and facilitates CERCLA's polluter-pays principle. EPA also notes that, as discussed in Section III.C of this preamble, it expects to focus on implementing the objectives of the PFAS Strategic Roadmap by holding responsible those who significantly contribute to the releases of these substances into the environment.

Comment: Numerous commenters expressed concerns that the designation will shift the costs of CERCLA cleanups of PFOA and PFOS from chemical and product manufacturers to various third parties, including water utilities, waste management utilities, airports, fire departments, State governments, farmers, and landowners. Another commenter claimed that utilities could be implicated as PRPs at both NPL and non-NPL sites—despite being potentially de minimis contributors to contamination—and, because of CERCLA's joint and several liability scheme, such parties could theoretically be held responsible for the entire cost of cleanup.

Many commenters argued that EPA's use of enforcement discretion will neither adequately address the liability concerns of certain public sector entities nor ensure that cleanups and settlements assign primary responsibility to parties that significantly contributed to contamination or otherwise profited from the conditions resulting in contamination.

Some commenters also requested that the Agency clarify how enforcement discretion would function in the context of PFOA- or PFOS-related contamination, particularly for water utilities. Finally, several commenters asked EPA to clarify that a CERCLA designation will not impact the land application of municipal biosolids in any way before finalizing this rulemaking.

Response: While EPA acknowledges that the designation has the potential to impact municipalities, EPA does not have information suggesting that designation will result in unusual liability outcomes. EPA recognizes that some parties who do not bear primary responsibility for contamination may be sued and face uncertain litigation costs. EPA believes that CERCLA's liability limitations, coupled with EPA enforcement discretion policies, should operate to minimize hardship for parties that did not significantly contribute to contamination. EPA expects that designation should not change CERCLA's liability framework and that CERCLA will continue to operate as it has for decades (with respect to the more than 800 existing hazardous substances) to resolve who should pay for the cleanup and how much.

EPA also disagrees with the commenters' position that designation will necessarily result in a shift of cleanup costs from PFOA or PFOS manufacturers, to utilities and other sectors. As the Agency describes in sections II.E.7 and VI.B., CERCLA liability does not inevitably flow from any particular release. The question of whether an entity may be subject to litigation or could be held liable under CERCLA involves both site and fact-specific analyses. Additionally, while one commenter raised the issue of incurring potential CERCLA liability despite de minimis contribution to contamination at Superfund sites, EPA notes that—as described in Section VI.B.2—the statute already includes several provisions that may limit liability or the financial impact of liability, including for de minimis parties.

EPA gave careful consideration to CERCLA's liability scheme, and the impact designation may have on CERCLA liability. EPA concluded that designation will not change CERCLA's liability framework. Designation does not automatically confer liability, nor does it alter CERCLA's statutory or regulatory framework for liability. EPA determined that existing limitations in CERCLA coupled with existing CERCLA enforcement policies are sufficient to mitigate concerns about liability that may arise after designation. No additional action is necessary to ensure that those limitations and policies continue to operate as they have for decades. Nonetheless, EPA intends to develop a policy, consistent with those limitations and policies, that explains EPA's priorities for CERCLA enforcement in the context of PFOA and PFOS releases. Please see Section VI.C. for a more detailed discussion. *See also* FY 2024–2027 National Enforcement and Compliance Initiatives.

Regarding the question about application of biosolids, please refer to section VII.A.3.

VIII. Summary of This Final Rule

The designation of PFOA and PFOS as hazardous substances would have three direct effects: (1) Reporting and notification obligations when there is a release of PFOA or PFOS, their salts or structural isomers above the reportable quantity, (2) obligations on the U.S. Government when it transfers or sells certain properties, and (3) an obligation on DOT to list and regulate CERCLA designated hazardous substances as HMTA hazardous materials.

A. Default Reportable Quantity

EPA is setting the RQ by operation of law at the statutory default of one pound pursuant to section 102(b) of CERCLA for PFOA and PFOS and their salts and structural isomers. EPA did not propose, nor is it including in this final action, a RQ adjustment for these substances. If the Agency chooses to propose adjusting the RQ in the future, it would do so through notice-and-comment rulemaking.

B. Direct Effects of Designating PFOA, PFOS, and Their Salts and Structural Isomers as Hazardous Substances

1. Release Reporting Requirements

Section 103 of CERCLA requires any person in charge of a vessel or facility to immediately notify the NRC when there is a release of a hazardous substance, as defined under CERCLA section 101(14), in an amount equal to or greater than the RQ for that substance. The reporting requirements are further codified in 40 CFR 302.6. As of the effective date of this action, any person in charge of a vessel or facility as soon as he or she has knowledge of a release from such vessel or facility of one pound or more of PFOA or PFOS, their salts or structural isomers in any 24-hour period is required to immediately notify the NRC in accordance with 40 CFR 302.6. CERCLA section 111(g) requires owners or operators of any vessel or facility to ''provide reasonable notice to potential injured parties by publication in local newspapers serving the affected area'' of a release of a hazardous substance.

In addition to these CERCLA reporting requirements, EPCRA section 304 requires owners or operators of facilities to immediately notify their SERC (or TERC) and LEPC (or TEPC) when there is a release at or above the reportable quantity of PFOA or PFOS, their salts or structural isomers in a 24-hour period. EPCRA section 304 also requires these facilities to submit a follow-up written report to the SERC (or TERC) and LEPC (or TEPC) within 30 days of the release. (*Note: Some states provide less than 30 days to submit the follow-up written report. Facilities are encouraged to contact the appropriate State or Tribal agency for additional reporting requirements.*) *See* 40 CFR part 355, subpart C, for information on the contents for the initial telephone notification and the follow-up written report.

EPCRA and CERCLA are separate, but interrelated, environmental laws that work together to provide emergency release notifications to Federal, State, Tribal, and local officials. Notice given to the NRC under CERCLA serves to inform the Federal government of a release so that Federal personnel can evaluate the need for a response in accordance with the National Oil and Hazardous Substances Contingency Plan, the Federal government's framework for responding to both oil and hazardous substance releases. The NRC maintains all reports of hazardous substance and oil releases made to the Federal government.

Relatedly, release notifications under EPCRA given to the SERC (or TERC) and to the LEPC (or TEPC) are crucial so that these State, Tribal, and local authorities have information to help protect the community.

2. Requirements Upon Transfer of Government Property

Under CERCLA section 120(h), when Federal agencies sell or transfer federally owned, real property, they must provide notice of when any hazardous substances ''was stored for one year or more, known to have been released, or disposed of'' and covenants concerning the remediation of such hazardous substances in certain circumstances. *https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap103-subchapI-sec9620.pdf.*

3. Requirement of DOT To List and Regulate CERCLA Hazardous Substances

Section 306(a) of CERCLA requires substances designated as hazardous under CERCLA to be listed and regulated as hazardous materials by DOT under the Hazardous Materials Transportation Act.

IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

This action is a ''significant regulatory action'', as defined under section 3(f)(1) of Executive Order 12866, as amended by Executive Order 14094. Accordingly, EPA, submitted this action to the Office of Management and Budget (OMB) for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, ''*Regulatory Impact Analysis of the Final Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as CERCLA Hazardous Substances*'', is also available in the docket and briefly summarized in *Section I, Executive Summary* of this action.

B. Paperwork Reduction Act

The information collection activities in this final rule have been submitted for approval to the OMB under the Paperwork Reduction Act. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2708.02, OMB Control No. 2050–0227. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The designation of PFOA and PFOS, and their salts and structural isomers, as hazardous substances require any person in charge of a vessel or facility that identifies a release of one pound or more within a 24-hour period of these substances to report the release to the NRC under section 103 of CERCLA and to the SERC (or TERC) and LEPC (or TEPC) under section 304 of EPCRA. The implementing regulations of CERCLA section 103 and EPCRA section 304 are codified at 40 CFR parts 302 and 355, respectively.

Respondents/affected entities: Any person in charge of a vessel or facility from which there is a release of PFOA or PFOS and their salts and structural isomers, equal to or greater than the RQ of one pound within 24 hours.

Respondent's obligation to respond: Mandatory under section 103 and section 111 of CERCLA and section 304 of EPCRA.

Estimated number of respondents: 0 to 614 releases per year.

Frequency of response: Varies.

Total estimated burden: 6,889 hours (per year) maximum. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: Approximately $1,630,000 (per year) maximum, includes approximately $585,000 annualized operation and maintenance costs (and no capital costs).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action, including importers and importers of articles that contain these

substances, are: (1) PFOA and/or PFOS manufacturers; (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream users of PFOA and PFOS; (5) downstream users of PFOA and/or PFOS products; (6) waste management facilities; and (7) wastewater treatment facilities. (*Note: PFOA and PFOS noted here include their salts and structural isomers*). The Agency has estimated that there may be up to 614 reported releases of PFOA or PFOS in any one year and that a small percentage of the annual reports will be submitted by small entities. As further context, even if the maximum number of reports (614) were created to account for every estimated release in a given year and all 614 of these reported releases were from the smallest of the small entities (as described in the RIA, defined using SBA size standards), only 2.5 percent of the 24,836 smallest of the small businesses identified by EPA would be affected. The estimated cost of $2,658 to report a release of PFOA or PFOS is not greater than one percent of the annual revenues for the typical small entity in any impacted industry. For example, estimated annual breakeven costs per facility are lowest for Reupholstery and Furniture Repair (NAICS 811420) at $3,591 at the one percent threshold. Given the estimated notification costs per release of $2,658, EPA does not expect a small business facility's cost to cross even the one percent threshold. Additionally, EPA considered how direct reporting costs may impact small governmental jurisdictions. The $2,658 reporting cost per release associated with the final rule represents 0.001 percent of average local government revenues serving a population of 50,000 or less, which is well below one percent. Further, for a local government serving just 100 residents, the $2,658 in costs for reporting represents 0.5 percent of these revenues, also well below a one percent threshold.

Details of this analysis are presented in Section 6.2 of the *Regulatory Impact Analysis of the Final Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as CERCLA Hazardous Substances,* available in the docket.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments that may result in expenditures, in the aggregate, or to the private sector, of $100 million or more in any one year.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

A. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. It does not have substantial direct effects on one or more Tribal Nations, on the relationship between the Federal Government and Tribal Nations, or on the distribution of power and responsibilities between the Federal Government and Tribal Nations. Thus, Executive Order 13175 does not apply to this action.

Designating PFOA and PFOS, and their salts and isomers as CERCLA hazardous substances triggers release reporting requirements under EPCRA section 304 in addition to the release notification requirement under CERCLA section 103. Under EPCRA section 304, facilities are required to immediately report any releases of these substances at or above the default RQ of one pound to the State, Tribal, and local implementing agencies. The associated reporting burden of this effort on Tribes is expected to be minimal and if release were to occur, and Tribal agencies would be able to take action, if necessary, to protect their community from exposure to these substances. If Tribal agencies do not have the resources to respond to an emergency situation, they may request assistance from the State or local emergency response agencies. Executive Order 13175 does not apply to this action.

Consistent with EPA's Policy on Consultation with Tribal Nations, EPA offered government-to-government consultation to all federally recognized Tribes during the development of this action. No Tribe requested consultation. EPA hosted a national Tribal informational webinar on September 7, 2022, to explain the action and answer questions (*https://clu-in.org/conf/tio/TribesPFOAPFOS_090722/*.)

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to Executive Order 13045 because it is a significant regulatory action under section 3(f)(1) of Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. Evidence indicates that exposure to PFOA and/or PFOS are associated with adverse health effects relevant to children, including developmental effects to fetuses during pregnancy or to breast-fed infants, cardiovascular effects and immune effects in children. Other evidence suggests that these substances are associated with endocrine and reproductive effects that impact development. Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk. Further information on all health effects of PFOA and PFOS is in section V. A. PFOA and PFOS Pose a Hazard. Accordingly, we have evaluated the environmental health or safety effects of PFAS exposures on children. The protection offered by using the suite of tools CERCLA provides to address prevalent PFAS contamination may be especially important for children because childhood represents a life stage associated with increased susceptibility to PFAS-related health effects, such as developmental effects.

Furthermore, EPA's *Policy on Children's Health* also applies to this action. Information on how the Policy was applied is available under ''Children's Environmental Health'' in section V. A. PFOA and PFOS Pose a Hazard of this preamble.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action designates PFOA and PFOS as CERCLA hazardous substances and does not involve the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

Executive Order 14096 (88 FR 25,251, Apr. 26, 2023) directs Federal agencies to advance the goal of environmental justice (EJ) for all. This action builds upon and supplements the efforts of Executive Order 12898 (59 FR 7629, February 16, 1994) to address EJ concerns.

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. The demographic analysis of plastics manufacturers, facilities reporting to the TRI, and U.S. airports found that people of color and low-income populations are disproportionately represented (except near small/medium airports). In particular, these sites have a higher percentage of people of color surrounding them relative to the national average. This finding holds whether focusing on assessing all populations within one or three miles of these sites or only populations served by private wells.

EPA believes that this action is likely to reduce existing disproportionate and adverse human health or environmental effects on communities with EJ concerns. To the extent that the final rule leads to additional response actions to mitigate or eliminate exposure to PFOA/PFOS, or to actions that mitigate exposure earlier, health risks for populations communities living near sites where releases occur may decline. Based on the above analysis, the proportion of the population near these sites identified as racial or ethnic minorities with various potential communities with EJ concerns or (in some cases) people living in structures with a higher probability of containing lead paint (built before 1960) exceeds the national average. Thus, EPA expects that the final rule will at least partially mitigate the existing burden of PFOS/PFOA exposure that falls disproportionately on communities with EJ concerns.

Potential exposure across several key demographic categories were analyzed relative to facilities with known historical use, releases, and/or known contamination of PFOA and PFOS (U.S. EPA, 2024e). Due to uncertainty regarding the location of future PFOA/PFOS releases, this analysis uses these facilities as a proxy for identifying where response actions for PFOA and PFOS may occur and provides demographic information about the surrounding populations. This analysis examines the following site types as proxies for facilities that may potentially be affected:

- Sites owned/operated by plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA [76]
- Sites owned/operated by companies reporting PFOS and PFOA releases (including PFOA and PFOS salts) to EPA's Toxic Release Inventory (TRI) (U.S. EPA, 2023e) [77]
- Operating U.S. airports and airfields [78]
  - Large U.S. airports and airfields
  - All other U.S. airports and airfields (*i.e.,* medium and small)

Areas around plastics material and resin manufacturer sites and/or sites reporting releases to TRI, on average, are in areas with higher concentrations of people of color, Black/African American residents, and households with a ratio of income to poverty level of two and below compared with national average. These areas also have much higher rates of structures built before 1960 which can have lead paint and lead to higher exposures of lead. These findings suggest that releases related to manufacturing facilities could have EJ implications, such as disproportionate adverse impacts on local communities. Additionally, on average, airports across the U.S. are surrounded by populations that generally reflect national averages in relevant demographic categories. Large airports, however, are more likely to be surrounded by higher rates of people of color relative to the U.S. population. A complete discussion of the analysis behind these findings is available in Section 6.3 of the RIA accompanying this rulemaking. These findings, combined with the uncertainty surrounding the location of future releases, are indicative of potential impacts but do not provide a clear indication of the type of disparities related to potential exposure to PFAS. Consistent with the policy priorities outlined in Executive Orders 14096 (The White House, 2023) and 14008 (The White House, 2021), EPA expects this regulation will have a beneficial impact on disadvantaged communities as well as populations or communities with EJ concerns. While the locations that may be affected by this final rule are uncertain, to the extent that these proxy locations are representative of likely locations, this screening analysis suggests that the designation may improve conditions for nearby populations potentially at risk of exposure, including communities with EJ concerns. To the extent that PFAS releases are consistent with the broader releases reported to TRI and typically involve disposal or manufacturing sites, demographic data around plastics material and resin manufacturer sites and historical releases may be a more reliable predictor of the type of community potentially affected by this proposed rulemaking. Specific site conditions and demographic patterns will determine the magnitude of effects on the surrounding human and natural environment. These details will likely become more apparent over time as EPA implements response actions and release reports are made, allowing for a more robust analysis of disproportionate and adverse outcomes experienced by populations communities with EJ concerns. This improved information would not increase risk for communities with EJ concerns and may improve the speed and design of response actions.

Further, the information supporting this Executive Order review is contained in the following sections in the preamble to this action: II.C., VI.A. and B. These sections explain that the

---

[76] Data acquired from: Environmental Protection Agency, ''Enforcement and Compliance History Online (ECHO)'', August 2023. Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this analysis uses proxy sites identified using sites owned/operated by companies that participated in EPA's PFOA Stewardship Program, under the assumption that the likelihood of PFOA/PFOS contamination is potentially high at these sites.

[77] TRI reporting is not currently required for isomers of PFOA and PFOS.

[78] Because the National Plan of Integrated Airport Systems (NPIAS) public facing dataset presented by the Federal Aviation Administration (FAA) does not contain geographic information, this analysis relies on data from the United Nations Office for the Coordination of Humanitarian Affairs. To assess the coverage of the UN database, this analysis cross-referenced the list of airports represented in both datasets; this exercise found that the UN data contained 98% of all airports listed in the NPIAS. Of the 2% of sites listed in the NPIAS but not in the UN database, about half were located in rural Alaska. Full citations of these datasets are presented below:

(1) United Nations Office for the Coordination of Humanitarian Affairs, ''The Humanitarian Data Exchange: Airports in the United States of America'', June 2021. Downloaded on June 18, 2021. Accessed at: *https://data.humdata.org/dataset/ourairports-usa.* The dataset categorized airports by the following size categories: small, medium, and large.

(2) Federal Aviation Administration. ''National Plan of Integrated Airport Systems (NPIAS)—Current—Airports'', October 07, 2020. Downloaded February 2022. Accessed at: *https://www.faa.gov/airports/planning_capacity/npias/current/.*

designation of PFOA and PFOS as hazardous substances and the required reporting and notification requirements, will result in more information about the location and extent of releases. This improved information does not increase risk or result in any adverse environmental justice impacts.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit the rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

References

Ahrens, L., Yeung, L.W., Taniyasu, S., Lam, P.K., & Yamashita, N. (2011, Oct). Partitioning of perfluorooctanoate (PFOA), perfluorooctane sulfonate (PFOS) and perfluorooctane sulfonamide (PFOSA) between water and sediment. *Chemosphere, 85*(5), 731–737. *https://doi.org/10.1016/j.chemosphere.2011.06.046*

Ankley, G.T., Kuehl, D.W., Kahl, M.D., Jensen, K.M., Butterworth, B.C., & Nichols, J.W. (2004, Nov). Partial life-cycle toxicity and bioconcentration modeling of perfluorooctanesulfonate in the northern leopard frog (Rana pipiens). *Environ Toxicol Chem, 23*(11), 2745–2755. *https://doi.org/10.1897/03-667*

Announcement of the Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, (2021). *https://www.federalregister.gov/documents/2021/03/03/2021-04184/announcement-of-final-regulatory-determinations-for-contaminants-on-the-fourth-drinking-wate*

ATSDR. (2021). *Toxicological profile for perfluoroalkyls.* Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, Public Health Service. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*

Bangma, J.T., Reiner, J.L., Jones, M., Lowers, R.H., Nilsen, F., Rainwater, T.R., Somerville, S., Guillette, L.J., & Bowden, J.A. (2017, Jan). Variation in perfluoroalkyl acids in the American alligator (*Alligator mississippiensis*) at Merritt Island National Wildlife Refuge. *Chemosphere, 166,* 72–79. *https://doi.org/10.1016/j.chemosphere.2016.09.088*

Barry, V., Winquist, A., & Steenland, K. (2013, Nov–Dec). Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environ Health Perspect, 121*(11–12), 1313–1318. *https://doi.org/10.1289/ehp.1306615*

Barry V., Darrow L.A., Klein M., Winquist A., Steenland K. Early life perfluorooctanoic acid (PFOA) exposure and overweight and obesity risk in adulthood in a community with elevated exposure. Environ Res. 2014 Jul;132:62–9. doi: 10.1016/j.envres.2014.03.025. Epub 2014 Apr 16. PMID: 24742729.

Ballesteros V., Costa O., Iñiguez C., Fletcher T., Ballester F., Lopez-Espinosa M.J. Exposure to perfluoroalkyl substances and thyroid function in pregnant women and children: A systematic review of epidemiologic studies. Environ Int. 2017 Feb;99:15–28. doi: 10.1016/j.envint.2016.10.015. Review. Full text available at: *https://www.sciencedirect.com/science/article/pii/S0160412016306195*

Bartell, S.M., & Vieira, V.M. (2021). Critical review on PFOA, kidney cancer, and testicular cancer. *J Air Waste Manag Assoc,* 71(6), 663–679. *https://doi.org/10.1080/10962247.2021.1909668*

Behrman, J.R., & Rosenzweig, M.R. (2004). Returns to birthweight. *Review of Economics and Statistics, 86*(2), 586–601. *https://doi.org/10.1162/003465304323031139*

Blake, B.E., & Fenton, S.E. (2020, Oct). Early life exposure to per- and polyfluoroalkyl substances (PFAS) and latent health outcomes: A review including the placenta as a target tissue and possible driver of peri- and postnatal effects. *Toxicology, 443,* 152565. *https://doi.org/10.1016/j.tox.2020.152565*

Breen, B.N., Schaeffer, E.V., & Gelber, B. (2001). *Memorandum: Use of CERCLA 106 to address enganderments that may also be addressed under other environmental statutes. https://www.epa.gov/sites/default/files/2013-10/documents/ise-crossmedia.pdf*

Budtz-Jorgensen, E., & Grandjean, P. (2018). Application of benchmark analysis for mixed contaminant exposures: Mutual adjustment of perfluoroalkylate substances associated with immunotoxicity. *PLoS One, 13*(10), e0205388. *https://doi.org/10.1371/journal.pone.0205388*

Burkhard, L.P. (2021, Jun). Evaluation of published bioconcentration factor (BCF) and bioaccumulation factor (BAF) data for per- and polyfluoroalkyl substances across aquatic species. *Environ Toxicol Chem, 40*(6), 1530–1543. *https://doi.org/10.1002/etc.5010*

Butenhoff, J.L., Kennedy, G.L., Jr., Chang, S.C., & Olsen, G.W. (2012, Aug 16). Chronic dietary toxicity and carcinogenicity study with ammonium perfluorooctanoate in Sprague-Dawley rats. *Toxicology, 298*(1–3), 1–13. *https://doi.org/10.1016/j.tox.2012.04.001*

Cadwallader, A., Greene, A., Holsinger, H., Lan, A., Messner, M., Simic, M., & Albert, R. (2022). A Bayesian hierarchical model for estimating national PFAS drinking water occurrence. *AWWA Water Science, 4*(3). *https://doi.org/10.1002/aws2.1284*

Calafat, A.M., Wong, L.Y., Kuklenyik, Z., Reidy, J.A., & Needham, L.L. (2007, Nov). Polyfluoroalkyl chemicals in the U.S. population: data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and comparisons with NHANES 1999–2000. *Environ Health Perspect, 115*(11), 1596–1602. *https://doi.org/10.1289/ehp.10598*

California EPA. (2021). *Proposed public health goals for perfluorooctanoic acid and perfluorooctane sulfonic acid in drinking water.* California Environmental Protection Agency. *https://oehha.ca.gov/media/downloads/crnr/pfoapfosphgdraft061021.pdf*

CDC. (2021). *National Health and Nutrition Examination Survey: NHANES questionnaires, datasets, and related documentation.* Centers for Disease Control and Prevention. *https://wwwn.cdc.gov/nchs/nhanes/Default.aspx*

CDC. (2022). *Per- and polyfluorinated substances (PFAS) factsheet.* Centers for Disease Control and Prevention. *https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html*

Chaikind, S., & Corman, H. (1991, Oct). The impact of low birthweight on special education costs. *J Health Econ, 10*(3), 291–311. *https://doi.org/10.1016/0167-6296(91)90031-h*

Chatterji, P., Kim, D., & Lahiri, K. (2014, Sep). Birth weight and academic achievement in childhood. *Health Econ, 23*(9), 1013–1035. *https://doi.org/10.1002/hec.3074*

Christensen, K.Y., Raymond, M., Blackowicz, M., Liu, Y., Thompson, B.A., Anderson, H.A., & Turyk, M. (2017, Apr). Perfluoroalkyl substances and fish consumption. *Environ Res, 154,* 145–151. *https://doi.org/10.1016/j.envres.2016.12.032*

Chu, C., Zhou, Y., Li, Q.Q., Bloom, M.S., Lin, S., Yu, Y.J., Chen, D., Yu, H.Y., Hu, L.W., Yang, B.Y., Zeng, X.W., & Dong, G.H. (2020, Feb). Are perfluorooctane sulfonate alternatives safer? New insights from a birth cohort study. *Environ Int, 135,* 105365. *https://doi.org/10.1016/j.envint.2019.105365*

Colaizy, T.T., Bartick, M.C., Jegier, B.J., Green, B.D., Reinhold, A.G., Schaefer, A.J., Bogen, D.L., Schwarz, E.B., Stuebe, A.M., Eunice Kennedy Shriver National Institute of Child, H., & Human Development Neonatal Research, N. (2016, Aug). Impact of optimized breastfeeding on the costs of necrotizing enterocolitis in extremely low birthweight infants. *J Pediatr, 175,* 100–105 e102. *https://doi.org/10.1016/j.jpeds.2016.03.040*

D'Agostino, R.B., Sr., Vasan, R.S., Pencina, M.J., Wolf, P.A., Cobain, M., Massaro, J.M., & Kannel, W.B. (2008, Feb 12). General cardiovascular risk profile for use in primary care: the Framingham Heart Study. *Circulation, 117*(6), 743–753. *https://doi.org/10.1161/CIRCULATIONAHA.107.699579*

Darrow, L.A., Stein, C.R., & Steenland, K. (2013, Oct). Serum perfluorooctanoic acid and perfluorooctane sulfonate concentrations in relation to birth outcomes in the Mid-Ohio Valley, 2005–2010. *Environ Health Perspect, 121*(10), 1207–1213. *https://doi.org/10.1289/ehp.1206372*

Dhingra R., Lally C., Darrow L.A., Klein M., Winquist A., Steenland K. Perfluorooctanoic acid and chronic kidney disease: Longitudinal analysis of a Mid-Ohio Valley community. Environ

Res. 2016 Feb;145:85–92. doi: 10.1016/j.envres.2015.11.018. Epub 2015 Dec 6. PubMed PMID: 26656498. Full text available at: *https://www.ncbi.nlm.nih.gov/pubmed/26802619*

Dobson, K.G., Ferro, M.A., Boyle, M.H., Schmidt, L.A., Saigal, S., & Van Lieshout, R.J. (2018, Oct). How do childhood intelligence and early psychosocial adversity influence income attainment among adult extremely low birth weight survivors? A test of the cognitive reserve hypothesis. *Dev Psychopathol, 30*(4), 1421–1434. *https://doi.org/10.1017/S0954579417001651*

Domingo, J.L., & Nadal, M. (2019). Human exposure to per- and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature. *Environmental Research, 177. https://doi.org/10.1016/j.envres.2019.108648*

Dzierlenga, M.W., Crawford, L., & Longnecker, M.P. (2020, Jun). Birth weight and perfluorooctane sulfonic acid: a random-effects meta-regression analysis. *Environ Epidemiol, 4*(3), e095. *https://doi.org/10.1097/EE9.0000000000000095*

Elder, T., Figlio, D., Imberman, S., & Persico, C. (2020). The role of neonatal health in the incidence of childhood disability. *American Journal of Health Economics, 6*(2), 216–250. *https://doi.org/10.1086/707833*

Emmett, E.A., Shofer, F. S., Zhang, H., Freeman, D., Desai, C., & Shaw, L. M. (2006, Aug). Community exposure to perfluorooctanoate: relationships between serum concentrations and exposure sources. *J Occup Environ Med, 48*(8), 759–770. *https://doi.org/10.1097/01.jom.0000232486.07658.74*

European Food Safety Authority. (2008, Jul). Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain. *EFSA Journal, 6*(7), 653. *https://doi.org/10.2903/j.efsa.2008.653*

Falk, S., Brunn, H., Schroter-Kermani, C., Failing, K., Georgii, S., Tarricone, K., & Stahl, T. (2012, Dec). Temporal and spatial trends of perfluoroalkyl substances in liver of roe deer (*Capreolus capreolus*). *Environ Pollut, 171,* 1–8. *https://doi.org/10.1016/j.envpol.2012.07.022*

FDA. (2021). *Testing food for PFAS and assessing dietary exposure.* U.S. Food and Drug Administration. *https://www.fda.gov/food/chemical-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure*

Field, J., Higgins, C., Deeb, R., Conder, J., (2017, Aug). FAQs Regarding PFASs Associated with AFFF Use at U.S. Military Sites. *ESTCP. https://apps.dtic.mil/sti/pdfs/AD1044126.pdf*

Frisbee S.J., Shankar A., Knox S.S., Steenland K., Savitz D.A., Fletcher T., Ducatman A.M. Perfluorooctanoic acid, perfluorooctanesulfonate, and serum lipids in children and adolescents: Results from the C8 Health Project.

Arch Pediatr Adolesc Med. 2010 Sep;164(9):860–9. doi: 10.1001/archpediatrics.2010.163 Full text available at: *http://archpedi.ama-assn.org/cgi/content/short/164/9/860*

Gaines, L.G.T. (2023, May). Historical and current usage of per- and polyfluoroalkyl substances (PFAS): A literature review. *Am J Ind Med, 66*(5), 353–378. *https://doi.org/10.1002/ajim.23362*

Gallo V., Leonardi G, Genser B, Lopez-Espinosa M–J, Frisbee S.J., Karlsson L., Ducatman A.M., Fletcher T. Serum Perfluorooctanoate (PFOA) and Perfluorooctane Sulfonate (PFOS) Concentrations and Liver Function Biomarkers in a Population with Elevated PFOA Exposure. Environ Health Perspect. 2012 May;120(5):655–660. Epub 2012 Jan 30. doi: 10.1289/ehp.1104436. Full text available at: *http://dx.doi.org/doi:10.1289/ehp.1104436*

Gewurtz, S.B., Martin, P.A., Letcher, R.J., Burgess, N.M., Champoux, L., Elliott, J.E., & Weseloh, D.V.C. (2016, Sep 15). Spatio-temporal trends and monitoring design of perfluoroalkyl acids in the eggs of gull (Larid) species from across Canada and parts of the United States. *Sci Total Environ, 565,* 440–450. *https://doi.org/10.1016/j.scitotenv.2016.04.149*

Giesy, J.P., & Kannan, K. (2001, Apr 1). Global distribution of perfluorooctane sulfonate in wildlife. *Environ Sci Technol, 35*(7), 1339–1342. *https://doi.org/10.1021/es001834k*

Goff, D.C., Jr., Lloyd-Jones, D.M., Bennett, G., Coady, S., D'Agostino, R.B., Gibbons, R., Greenland, P., Lackland, D.T., Levy, D., O'Donnell, C.J., Robinson, J. G., Schwartz, J.S., Shero, S.T., Smith, S.C., Jr., Sorlie, P., Stone, N.J., Wilson, P.W., Jordan, H.S., Nevo, L., Wnek, J., Anderson, J.L., Halperin, J.L., Albert, N.M., Bozkurt, B., Brindis, R.G., Curtis, L.H., DeMets, D., Hochman, J.S., Kovacs, R.J., Ohman, E.M., Pressler, S.J., Sellke, F.W., Shen, W.K., Smith, S.C., Jr., Tomaselli, G. F., & American College of Cardiology/American Heart Association Task Force on Practice, G. (2014, Jun 24). 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation, 129*(25 Suppl 2), S49–73. *https://doi.org/10.1161/01.cir.0000437741.48606.98*

Goodrich, J.A., Walker, D., Lin, X., Wang, H., Lim, T., McConnell, R., Conti, D.V., Chatzi, L., & Setiawan, V.W. (2022, Oct). Exposure to perfluoroalkyl substances and risk of hepatocellular carcinoma in a multiethnic cohort. *JHEP Rep, 4*(10), 100550. *https://doi.org/10.1016/j.jhepr.2022.100550*

Govarts, E., Remy, S., Bruckers, L., Den Hond, E., Sioen, I., Nelen, V., Baeyens, W., Nawrot, T.S., Loots, I., Van Larebeke, N., & Schoeters, G. (2016, May 12). Combined effects of prenatal exposures to environmental chemicals on birth weight. *Int J Environ Res Public Health, 13*(5). *https://doi.org/10.3390/ijerph13050495*

Graber, J. M., Alexander, C., Laumbach, R.J., Black, K., Strickland, P.O., Georgopoulos, P.G., Marshall, E.G., Shendell, D.G., Alderson, D., Mi, Z., Mascari, M., & Weisel, C.P. (2019, Mar). Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013–2014 NHANES. *J Expo Sci Environ Epidemiol, 29*(2), 172–182. *https://doi.org/10.1038/s41370-018-0096-z*

Grandjean, P., Andersen, E. W., Budtz-Jorgensen, E., Nielsen, F., Molbak, K., Weihe, P., & Heilmann, C. (2012, Jan 25). Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *JAMA, 307*(4), 391–397. *https://doi.org/10.1001/jama.2011.2034*

Grandjean, P., Heilmann, C., Weihe, P., Nielsen, F., Mogensen, U.B., & Budtz-Jorgensen, E. (2017, Jul 26). Serum vaccine antibody concentrations in adolescents exposed to perfluorinated compounds. *Environ Health Perspect, 125*(7), 077018. *https://doi.org/10.1289/EHP275*

Grandjean, P., Heilmann, C., Weihe, P., Nielsen, F., Mogensen, U.B., Timmermann, A., & Budtz-Jorgensen, E. (2017, Dec). Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. J Immunotoxicol, 14(1), 188–195. *https://doi.org/10.1080/1547691X.2017.1360968*

Guidelines for Using the Imminent Hazard, Enforcement and Emergency Response Authorities of Superfund and Other Statutes, 47 FR20664, May 13, 1982, available at *https://www.epa.gov/sites/default/files/2020-05/documents/imminent-hazard-response-enf-1982.pdf*

Hall, S.M., Patton, S., Petreas, M., Zhang, S., Phillips, A.L., Hoffman, K., & Stapleton, H.M. (2020, Nov 17). Per- and polyfluoroalkyl substances in dust collected from residential homes and fire stations in North America. *Environ Sci Technol, 54*(22), 14558–14567. *https://doi.org/10.1021/acs.est.0c04869*

Hall, Samantha M., Sharon Zhang, George H. Tait, Kate Hoffman, David N. Collier, Jane A. Hoppin, Heather M. Stapleton, PFAS levels in paired drinking water and serum samples collected from an exposed community in Central North Carolina, Science of The Total Environment, Volume 895, 2023, 165091, *https://doi.org/10.1016/j.scitotenv.2023.165091.*

Hanssen, L., Dudarev, A.A., Huber, S., Odland, J.O., Nieboer, E., & Sandanger, T.M. (2013, Mar 1). Partition of perfluoroalkyl substances (PFASs) in whole blood and plasma, assessed in maternal and umbilical cord samples from inhabitants of arctic Russia and Uzbekistan. *Sci Total Environ, 447,* 430–437. *https://doi.org/10.1016/j.scitotenv.2013.01.029*

Hines, C.T., Padilla, C.M., & Ryan, R.M. (2020, May). The effect of birth weight on child development prior to school entry. *Child Dev, 91*(3), 724–732. *https://doi.org/10.1111/cdev.13355*

Hoffman, K., Webster, T.F., Bartell, S.M., Weisskopf, M.G., Fletcher, T., Vieira,

V.M., (2011, Jan). Private drinking water wells as a source of exposure to perfluorooctanoic acid (PFOA) in communities surrounding a fluoropolymer production facility

Holmstrom, K.E., Jarnberg, U., & Bignert, A. (2005, Jan 1). Temporal trends of PFOS and PFOA in guillemot eggs from the Baltic Sea, 1968–2003. *Environ Sci Technol, 39*(1), 80–84. *https://doi.org/10.1021/es049257d*

Institute of Medicine. (2007). *Preterm birth: causes, consequences, and prevention* (R.E. Behrman & A.S. Butler, Eds.). National Academies Press. *https://doi.org/10.17226/11622*

Jelenkovic, A., Mikkonen, J., Martikainen, P., Latvala, A., Yokoyama, Y., Sund, R., Vuoksimaa, E., Rebato, E., Sung, J., Kim, J., Lee, J., Lee, S., Stazi, M. A., Fagnani, C., Brescianini, S., Derom, C. A., Vlietinck, R.F., Loos, R.J.F., Krueger, R.F., McGue, M., Pahlen, S., Nelson, T.L., Whitfield, K. E., Brandt, I., Nilsen, T.S., Harris, J.R., Cutler, T.L., Hopper, J.L., Tarnoki, A. D., Tarnoki, D.L., Sorensen, T.I. A., Kaprio, J., & Silventoinen, K. (2018, Sep). Association between birth weight and educational attainment: an individual-based pooled analysis of nine twin cohorts. *J Epidemiol Community Health, 72*(9), 832–837. *https://doi.org/10.1136/jech-2017-210403*

Joyce, C., Goodman-Bryan, M., & Hardin, A. (2012). *Preterm birth and low birth weight. http://www.urbanchildinstitute.org/sites/all/files/2010-10-01-PTB-and-LBW.pdf*

Klein, R., & Lynch, M. (2018). *Development of medical cost estimates for adverse birth outcomes.* U.S. EPA National Center for Environmental Economics.

Kotlarz, N., McCord, J., Collier, D., Lea, C.S., Strynar, M., Lindstrom, A.B., Wilkie, A.A., Islam, J.Y., Matney, K., Tarte, P., Polera, M.E., Burdette, K., DeWitt, J., May, K., Smart, R.C., Knappe, D.R.U., & Hoppin, J.A. (2020, Jul). Measurement of Novel, Drinking Water-Associated PFAS in Blood from Adults and Children in Wilmington, North Carolina. *Environ Health Perspect, 128*(7), 77005. *https://doi.org/10.1289/EHP6837*

Kowlessar, N.M., Jiang, H.J., & Steiner, C. (2013). *Hospital stays for newborns, 2011* (Statistical Brief #163). Agency for Healthcare Research and Quality. *https://www.ncbi.nlm.nih.gov/books/NBK173954/*

Langenbach, B., & Wilson, M. (2021, Oct 23). Per- and polyfluoroalkyl substances (PFAS): significance and considerations within the regulatory framework of the USA. *Int J Environ Res Public Health, 18*(21). *https://doi.org/10.3390/ijerph182111142*

Lau, C., Thibodeaux, J.R., Hanson, R.G., Narotsky, M.G., Rogers, J.M., Lindstrom, A.B., & Strynar, M.J. (2006, Apr). Effects of perfluorooctanoic acid exposure during pregnancy in the mouse. *Toxicol Sci, 90*(2), 510–518. *https://doi.org/10.1093/toxsci/kfj105*

Lloyd-Jones, D.M., Huffman, M.D., Karmali, K.N., Sanghavi, D.M., Wright, J.S., Pelser, C., Gulati, M., Masoudi, F. A., & Goff, D.C., Jr. (2017, Mar 28). Estimating longitudinal risks and benefits from cardiovascular preventive therapies among medicare patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A special report from the American Heart Association and American College of Cardiology. *J Am Coll Cardiol, 69*(12), 1617–1636. *https://doi.org/10.1016/j.jacc.2016.10.018*

Lou, I., Wambaugh, J.F., Lau, C., Hanson, R.G., Lindstrom, A.B., Strynar, M.J., Zehr, R.D., Setzer, R.W., & Barton, H.A. (2009, Feb). Modeling single and repeated dose pharmacokinetics of PFOA in mice. *Toxicol Sci, 107*(2), 331–341. *https://doi.org/10.1093/toxsci/kfn234*

Loveless, S.E., Finlay, C., Everds, N.E., Frame, S.R., Gillies, P.J., O'Connor, J.C., Powley, C.R., & Kennedy, G.L. (2006, Mar 15). Comparative responses of rats and mice exposed to linear/branched, linear, or branched ammonium perfluorooctanoate (APFO). *Toxicology, 220*(2–3), 203–217. *https://doi.org/10.1016/j.tox.2006.01.003*

Malits, J., Blustein, J., Trasande, L., & Attina, T.M. (2018, Mar). Perfluorooctanoic acid and low birth weight: Estimates of U.S. attributable burden and economic costs from 2003 through 2014. *Int J Hyg Environ Health, 221*(2), 269–275. *https://doi.org/10.1016/j.ijheh.2017.11.004*

MDIFW. (2023). *PFAS Do Not Eat Advisory: For deer and wild turkey in portions of Fairfield and Skowhegan.* Maine Department of Inland Fisheries and Wildlife. *https://www.maine.gov/ifw/hunting-trapping/hunting/laws-rules/pfas-related-consumption-advisory.html*

Michigan PFAS Action Response Team. (2021). *PFAS in deer.* Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/fishandwildlife/deer*

Michigan PFAS Action Response Team. (2023). *PFAS in fish.* Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/fishandwildlife/fish*

Morganti, M., Polesello, S., Pascariello, S., Ferrario, C., Rubolini, D., Valsecchi, S., & Parolini, M. (2021, Jul). Exposure assessment of PFAS-contaminated sites using avian eggs as a biomonitoring tool: A frame of reference and a case study in the Po River valley (Northern Italy). *Integr Environ Assess Manag, 17*(4), 733–745. *https://doi.org/10.1002/ieam.4417*

NCDHHS. (2023). *NCDHHS recommends limiting fish consumption from the Middle and Lower Cape Fear River due to contamination with ''forever chemicals''.* North Carolina Department of Health and Human Services. *https://www.ncdhhs.gov/news/press-releases/2023/07/13/ncdhhs-recommends-limiting-fish-consumption-middle-and-lower-cape-fear-river-due-contamination*

Negri, E., Metruccio, F., Guercio, V., Tosti, L., Benfenati, E., Bonzi, R., La Vecchia, C., & Moretto, A. (2017, Jul). Exposure to PFOA and PFOS and fetal growth: a critical merging of toxicological and epidemiological data. *Crit Rev Toxicol, 47*(6), 482–508. *https://doi.org/10.1080/10408444.2016.1271972*

Ng, C.A., & Hungerbuhler, K. (2014, May 6). Bioaccumulation of perfluorinated alkyl acids: observations and models. *Environ Sci Technol, 48*(9), 4637–4648. *https://doi.org/10.1021/es404008g*

Nicoletti, C., Salvanes, K.G., & Tominey, E. (2018). Response of parental investments to child's health endowment at birth. In *Health Econometrics* (pp. 175–199). *https://doi.org/10.1108/s0573-855520180000294009*

NJ DEQ. (2023). *PFAS standards and regulations. https://dep.nj.gov/pfas/standards/*

NTP. (2020). *NTP technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid (CASRN 335–67–1) administered in feed to Sprague Dawley (Hsd:Sprague Dawley® SD®) rats* (NTP TR 598). National Toxicology Program. *https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr598_508.pdf?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=tr598*

Obsekov, V., Kahn, L.G., & Trasande, L. (2023). Leveraging systematic reviews to explore disease burden and costs of per- and polyfluoroalkyl substance exposures in the United States. *Expo Health, 15*(2), 373–394. *https://doi.org/10.1007/s12403-022-00496-y*

Olsen, G.W., Mair, D.C., Lange, C.C., Harrington, L.M., Church, T.R., Goldberg, C.L., Herron, R.M., Hanna, H., Nobiletti, J.B., Rios, J.A., Reagen, W.K., & Ley, C.A. (2017, Aug). Per- and polyfluoroalkyl substances (PFAS) in American Red Cross adult blood donors, 2000–2015. *Environ Res, 157,* 87–95. *https://doi.org/10.1016/j.envres.2017.05.013*

Osuchukwu, O.O., & Reed, D.J. (2022). *Small for gestational age.* StatPearls Publishing. *https://www.ncbi.nlm.nih.gov/books/NBK563247/*

PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638 (2023). *https://www.federalregister.gov/documents/2023/03/29/2023-05471/pfas-national-primary-drinking-water-regulation-rulemaking#h-72*

PFAS Project Lab. (2019). *PFAS contamination is an equity issue, and President Trump's EPA is failing to fix it. https://pfasproject.com/2019/10/31/pfas-contamination-is-an-equity-issue-and-president-trumps-epa-is-failing-to-fix-it/*

Raleigh, K.K., Alexander, B.H., Olsen, G.W., Ramachandran, G., Morey, S.Z., Church, T.R., Logan, P.W., Scott, L.L., & Allen, E.M. (2014, Jul). Mortality and cancer incidence in ammonium perfluorooctanoate production workers. *Occup Environ Med, 71*(7), 500–506. *https://doi.org/10.1136/oemed-2014-102109*

Sagiv, S.K., Rifas-Shiman, S.L., Fleisch, A.F., Webster, T.F., Calafat, A.M., Ye, X., Gillman, M.W., & Oken, E. (2018, Apr 1). Early-pregnancy plasma concentrations of perfluoroalkyl substances and birth outcomes in Project Viva: confounded by pregnancy hemodynamics? *Am J Epidemiol, 187*(4), 793–802. *https://doi.org/10.1093/aje/kwx332*

Savitz, D.A., Stein, C.R., Elston, B., Wellenius, G.A., Bartell, S.M., Shin H–M, Vieira, V.M., Fletcher T. Relationship of Perfluorooctanoic Acid Exposure to Pregnancy Outcome Based on Birth Records in the Mid-Ohio Valley. Environ Health Perspect. 2012 Mar 26. doi: 10.1289/ehp.1104752 Full text available at: *http://dx.doi.org/doi:10.1289/ehp.1104752*

Shearer, J.J., Callahan, C.L., Calafat, A.M., Huang, W.Y., Jones, R.R., Sabbisetti, V.S., Freedman, N.D., Sampson, J.N., Silverman, D.T., Purdue, M.P., & Hofmann, J.N. (2021, May 4). Serum concentrations of per- and polyfluoroalkyl substances and risk of renal cell carcinoma. *J Natl Cancer Inst, 113*(5), 580–587. *https://doi.org/10.1093/jnci/djaa143*

Starling, A.P., Adgate, J.L., Hamman, R.F., Kechris, K., Calafat, A.M., Ye, X., & Dabelea, D. (2017). Perfluoroalkyl substances during pregnancy and offspring weight and adiposity at birth: examining mediation by maternal fasting glucose in the Healthy Start Study. *Environmental Health Perspectives, 125*(6). *https://doi.org/10.1289/ehp641*

Steenland, K., & Woskie, S. (2012, Nov 15). Cohort mortality study of workers exposed to perfluorooctanoic acid. *Am J Epidemiol, 176*(10), 909–917. *https://doi.org/10.1093/aje/kws171*

Steenland, K., S. Tinker, S. Frisbee, A. Ducatman, V. Vaccarino. Association of perfluorooctanoic acid and perfluorooctane sulfonate with serum lipids among adults living near a chemical plant. Am. J. Epidemiol., 170 (10) (2009), pp. 1268–1278, 10.1093/aje/kwp279

Steenland, K., Barry, V., Savitz, D. Serum perfluorooctanoic acid and birthweight: an updated meta-analysis with bias analysis. Epidemiology 2018 Nov;29(6):765–776. doi: 10.1097/EDE.0000000000000903. PMID: 30063543

Steenland, K., Kugathasan, S., Barr, D.B. PFOA and ulcerative colitis. Environ Res. 2018 Aug;165:317–321. doi: 10.1016/j.envres.2018.05.007. Epub 2018 May 16. PubMed PMID: 29777922; PubMed Central PMCID: PMC6358414. Full text available at: *https://www.ncbi.nlm.nih.gov/pubmed/29777922*

Steenland, K., Tinker, S., Frisbee, S., Ducatman, A., Vaccarino, V. Association of perfluorooctanoic acid and perfluorooctane sulfonate with serum lipids among adults living near a chemical plant. Am J Epidemiol. 2009 Nov 15;170(10):1268–78. Epub 2009 Oct 21. doi: 10.1093/aje/kwp279. Full text available at: *http://aje.oxfordjournals.org/cgi/content/abstract/kwp279*

Strynar, M.J., & Lindstrom, A.B. (2008, May 15). Perfluorinated compounds in house dust from Ohio and North Carolina, USA. *Environ Sci Technol, 42*(10), 3751–3756. *https://doi.org/10.1021/es7032058*

Taylor, L.O., Phaneuf, D.J., & Liu, X. (2016). *Disentangling property value impacts of environmental contamination from locally undesirable land uses: Implications for measuring post-cleanup stigma. https://cenrep.ncsu.edu/cenrep/wp-content/uploads/2015/07/TPL_complete.pdf*

Temple, J.A., Reynolds, A.J., & Arteaga, I. (2010, Sep). Low birth weight, preschool education, and school remediation. *Educ Urban Soc, 42*(6), 705–729. *https://doi.org/10.1177/0013124510370946*

The White House. (1994). *Presidential documents: Executive order 12898 of February 11, 1994: Federal actions to address environmental justice in minority populations and low-income populations. https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf*

The White House. (2021). *Executive order on tackling the climate crisis at home and abroad. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/*

Timmermann, C.A.G., Pedersen, H.S., Weihe, P., Bjerregaard, P., Nielsen, F., Heilmann, C., & Grandjean, P. (2022, Jan). Concentrations of tetanus and diphtheria antibodies in vaccinated Greenlandic children aged 7–12 years exposed to marine pollutants, a cross sectional study. *Environ Res, 203,* 111712. *https://doi.org/10.1016/j.envres.2021.111712*

U.S. EPA. (1991). *Guidance: Owners of residential property at Superfund sites. https://www.epa.gov/enforcement/guidance-owners-residential-property-superfund-sites*

U.S. EPA. (1995). *Final policy toward owners of property containing contaminated aquifers.* U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2013-09/documents/contamin-aqui-rpt.pdf*

U.S. EPA. (2005). *Guidelines for carcinogen risk assessment* (EPA/630/P–03/001F). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf*

U.S. EPA. (2016a). *Drinking water health advisory for perfluorooctane sulfonate (PFOS)* (EPA822R16004). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf*

U.S. EPA. (2016b). *Drinking water health advisory for perfluorooctanoic acid (PFOA)* (EPA822R16005). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf*

U.S. EPA. (2016c). *Health effects support document for perfluorooctane sulfonate (PFOS).* U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf*

U.S. EPA. (2016d). *Health effects support document for perfluorooctanoic acid (PFOA).* U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf*

U.S. EPA. (2016e). *Six-year review 3—Health effects assessment for existing chemical and radionuclide national primary drinking water regulations—Summary report* (EPA 822–R–16–008). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-12/documents/822r16008.pdf*

U.S. EPA. (2017). *The third Unregulated Contaminant Monitoring Rule (UCMR 3): Data summary, January 2017* (EPA815S17001). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf*

U.S. EPA. (2019a). *EPA's per- and polyfluoroalkyl substances (PFAS) action plan* (EPA823R18004). U.S. Environmental Protection Agency. *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100W32I.txt*

U.S. EPA. (2019b). *Fish and shellfish program newsletter* (EPA823N19002). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/production/files/2019-04/documents/fish-news-mar2019.pdf*

U.S. EPA. (2020). *Interim guidance on the destruction and disposal of perfluoroalkyl and polyfluoroalkyl substances and materials containing perfluoroalkyl and polyfluoroalkyl substances. Interim guidance for public comment.* U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf*

U.S. EPA. (2021a). *PFAS strategic roadmap: EPA's commitments to action 2021–2024.* U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf*

U.S. EPA. (2021b). *Proposed approaches to the derivation of a draft maximum contaminant level goal for perfluorooctanoic acid (PFOA) (CASRN 335–67–1) in drinking water. External Peer Review Draft* (EPA 822D21001). U.S. Environmental Protection Agency.

U.S. EPA. (2022). *Science Advisory Board. Review of EPA's analysis to support EPA's national primary drinking water rulemaking for PFAS* (EPA–SAB–22–008). U.S. Environmental Protection Agency.

U.S. EPA. (2023a). *Fact sheet: 2010/2015 PFOA Stewardship Program. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program*

U.S. EPA. (2023b). *Hazard Ranking System (HRS). https://www.epa.gov/superfund/hazard-ranking-system-hrs*

U.S. EPA. (2023c). *PFOA Stewardship Program baseline year summary report.* U.S. Environmental Protection Agency. *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/pfoa-stewardship-program-baseline-year-summary-report*

U.S. EPA. (2023d). *Risk management for per- and polyfluoroalkyl substances (PFAS) under TSCA. https://www.epa.gov/assessing-and-managing-chemicals-*

under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas
U.S. EPA. (2023e). *Toxics Release Inventory (TRI) Program, 2022 TRI preliminary dataset: Basic data files.* U.S. Environmental Protection Agency. *https://www.epa.gov/toxics-release-inventory-tri-program/tri-basic-data-files-calendar-years-1987-present*
U.S. EPA. (2023f). *What EPA is doing to reduce mercury pollution, and exposures to mercury. https://www.epa.gov/mercury/what-epa-doing-reduce-mercury-pollution-and-exposures-mercury#discharged*
U.S. EPA. (2023g). *Public Comment Draft: Toxicity assessment and proposed maximum contaminant level goal (MCLG) for perfluorooctane sulfonic acid (PFOS) (CASRN 1763–23–1) in drinking water* (EPA–822–P–23–007). U.S. Environmental Protection Agency.
U.S. EPA. (2023h). *Public Comment Draft: Toxicity assessment and proposed maximum contaminant level goal (MCLG) for perfluorooctanoic acid (PFOA) (CASRN 335–67–1) in drinking water* (EPA–822–P–23–005). U.S. Environmental Protection Agency.
U.S. EPA (2023i) *National Rivers and Streams Assessment: The Third Collaborative Survey.* EPA 841–R–22–004. U.S. Environmental Protection Agency, Office of Water and Office of Research and Development. *https://riverstreamassessment.epa.gov/webreport*
U.S. EPA. (2024a). *National Primary Drinking Water Regulation for PFAS.*
U.S. EPA. (2024b). *Office of Water final human health toxicity assessment for perfluorooctane sulfonic acid (PFOS).*
U.S. EPA. (2024c). *Office of Water final human health toxicity assessment for perfluorooctanoic acid (PFOA).*
U.S. EPA. (2024d). *Office of Water final maximum contaminant level goals (MCLGs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water.*
U.S. EPA. (2024e). *Regulatory impact analysis of the final rulemaking to designate perfluorooctanoic acid and perfluorooctanesulfonic acid as CERCLA hazardous substances.* U.S. Environmental Protection Agency.
Uhlmann, D. M. (2023). *Memorandum: FY 2024–2027 national enforcement and compliance initiatives.* U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2023-08/fy2024-27necis.pdf*
USDA. (2021). *Analytical results for PFAS in 2018 produce sampling.* U.S. Department of Agriculture. *https://www.fda.gov/media/127848/download?attachment*
Verner, M.A., Loccisano, A.E., Morken, N.H., Yoon, M., Wu, H., McDougall, R., Maisonet, M., Marcus, M., Kishi, R., Miyashita, C., Chen, M.H., Hsieh, W.S., Andersen, M.E., Clewell, H.J., 3rd, & Longnecker, M.P. (2015, Dec). Associations of perfluoroalkyl substances (PFAS) with lower birth weight: An Evaluation of potential confounding by glomerular filtration rate using a physiologically based pharmacokinetic model (PBPK). *Environ Health Perspect, 123*(12), 1317–1324. *https://doi.org/10.1289/ehp.1408837*
Vieira, V.M., Hoffman, K., Shin, H.M., Weinberg, J.M., Webster, T.F., & Fletcher, T. (2013, Mar). Perfluorooctanoic acid exposure and cancer outcomes in a contaminated community: a geographic analysis. *Environ Health Perspect, 121*(3), 318–323. *https://doi.org/10.1289/ehp.1205829*
Wang, Y., Yeung, L.W.Y., Yamashita, N., Taniyasu, S., So, M.K., Murphy, M.B., & Lam, P.K.S. (2008). Perfluorooctane sulfonate (PFOS) and related fluorochemicals in chicken egg in China. *Chinese Science Bulletin, 53*(4), 501–507. *https://doi.org/10.1007/s11434-008-0128-5*
Waterfield, G., Rogers, M., Grandjean, P., Auffhammer, M., & Sunding, D. (2020, Apr 22). Reducing exposure to high levels of perfluorinated compounds in drinking water improves reproductive outcomes: evidence from an intervention in Minnesota. *Environ Health, 19*(1), 42. *https://doi.org/10.1186/s12940-020-00591-0*
Wikstrom, S., Lin, P.I., Lindh, C.H., Shu, H., & Bornehag, C.G. (2020, May). Maternal serum levels of perfluoroalkyl substances in early pregnancy and offspring birth weight. *Pediatr Res, 87*(6), 1093–1099. *https://doi.org/10.1038/s41390-019-0720-1*
Wisconsin DNR. (2020). *DNR And DHS issue do not eat advisory for deer liver in five-mile area surrounding JCI/TYCO site in Marinette https://dnr.wisconsin.gov/newsroom/release/37921*
Yao, Q., Gao, Y., Zhang, Y., Qin, K., Liew, Z., & Tian, Y. (2021). Associations of paternal and maternal per- and polyfluoroalkyl substances exposure with cord serum reproductive hormones, placental steroidogenic enzyme and birth weight. *Chemosphere, 285. https://doi.org/10.1016/j.chemosphere.2021.131521*
Zahm, S., Bonde, J.P., Chiu, W.A., Hoppin, J., Kanno, J., Abdallah, M., et al. Carcinogenicity of perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). Lancet Oncol, Published online 30 November 2023; *https://doi.org/10.1016/S1470-2045(23)00622-8*
Zhang, Y., Mustieles, V., Wang, Y.X., Sun, Q., Coull, B., Sun, Y., Slitt, A., & Messerlian, C. (2023, Feb 14). Red blood cell folate modifies the association between serum per- and polyfluoroalkyl substances and antibody concentrations in U.S. adolescents. *Environ Sci Technol, 57*(6), 2445–2456. *https://doi.org/10.1021/acs.est.2c07152*

List of Subjects in 40 CFR Part 302

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Michael S. Regan,
Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 302 as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

■ 1. The authority citation for part 302 continues to read as follows:

Authority: 33 U.S.C. 1251 et. seq., 42 U.S.C. 9601, 42 U.S.C. 9602, 42 U.S.C. 9603

■ 2. Amend § 302.4:
■ a. By revising ''Note II to Table 302.4''.
■ b. In ''Table 302.4'' by adding, in alphabetical order, entries for ''Perfluorooctanesulfonic acid, salts, & structural isomers[v]'', ''Perfluorooctanesulfonic acid[v]'', Perfluorooctanoic acid, salts, & structural isomers[v]'', and ''Perfluorooctanoic acid[v]'';
■ c. In Appendix A to § 302.4 by adding in numerical order entries for ''335–67–1'' and ''1763–23–1''.

The revision and additions read as follows:

§ 302.4 Hazardous substances and reportable quantities.

* * * * *

Note II to Table 302.4

Hazardous substances are given a Statutory Code based on their statutory source. The ''Statutory Code'' column indicates the statutory source for designating each substance as a CERCLA hazardous substance. Statutory Code ''1'' indicates a Clean Water Act (CWA) Hazardous Substance [40 CFR 116.4; 33 U.S.C. 1321(b)(2)(A)]. Statutory Code ''2'' indicates a CWA Toxic Pollutant [40 CFR 401.15, 40 CFR part 423 Appendix A, and/or 40 CFR 131.36; 33 U.S.C. 1317(a)]. Statutory Code ''3'' indicates a CAA HAP [42 U.S.C. 7412(b); Pub. L. 101–549 November 15, 1990; 70 FR 75047 December 19, 2005; 69 FR 69320 November 29, 2004; 61 FR 30816 June 18, 1996; 65 FR 47342 August 2, 2000; 87 FR 393 January 5, 2022]. Statutory Code ''4'' indicates Resource Conservation and Recovery Act (RCRA) Hazardous Wastes [40 CFR part 261 Subpart D—Lists of Hazardous Wastes; 42 U.S.C. 6921]. (Note: The ''RCRA waste No.'' column provides the waste identification numbers assigned by RCRA regulations). Statutory Code ''5'' indicates a hazardous substance designated under section 102(a) of CERCLA. The ''Final RQ [pounds (kg)]'' column provides the reportable quantity for each hazardous substance in pounds and kilograms.

* * * * *

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES

Hazardous substance	CASRN	Statutory code	RCRA waste No.	Final RQ [pounds (kg)]
*	*	*	*	*
Perfluorooctanesulfonic acid, salts, & structural isomers [v]	N.A.	5		1 (0.454)
Perfluorooctanesulfonic acid [v]	1763–23–1	5		1 (0.454)
Perfluorooctanoic acid, salts, & structural isomers [v]	N.A.	5		1 (0.454)
Perfluorooctanoic acid [v]	335–67–1	5		1 (0.454)
*	*	*	*	*

[v] The Agency may adjust the statutory RQ for this hazardous substance in a future rulemaking; until then the statutory one-pound RQ applies.

* * * * *

Appendix A to § 302.4—Sequential CAS Registry Number List of CERCLA Hazardous Substances

CASRN	Hazardous substance
* * *	* * * *
335–67–1	Perfluorooctanoic acid
* * *	* * * *
1763–23–1	Perfluorooctanesulfonic acid

* * * * *

[FR Doc. 2024–08547 Filed 5–7–24; 8:45 am]

BILLING CODE 6560–50–P

information, please see the information provided in the **ADDRESSES** section of this document.

Dated: August 26, 2022.

Daniel Blackman

Regional Administrator, Region 4.

[FR Doc. 2022–19202 Filed 9–2–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 302

[EPA–HQ–OLEM–2019–0341; FRL–7204–02–OLEM]

RIN 2050–AH09

Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA'' or ''Superfund''), the Environmental Protection Agency (EPA or the Agency) is proposing to designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers, as hazardous substances. CERCLA authorizes the Administrator to promulgate regulations designating as hazardous substances such elements, compounds, mixtures, solutions, and substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. Such a designation would ultimately facilitate cleanup of contaminated sites and reduce human exposure to these ''forever'' chemicals.

DATES: Comments must be received on or before November 7, 2022. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before October 6, 2022.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0341, by any of the following methods:

• *Federal eRulemaking Portal: https://www.regulations.gov (our preferred method).* Follow the online instructions for submitting comments.

• *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, OLEM Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

• *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michelle Schutz, Office of Superfund Remediation and Technology Innovation (5202T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 703–346–9536; email address: *schutz.michelle@epa.gov.*

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations: We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of the preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ADEC Alaska Department of Environmental Conservation
AFFF Aqueous film-forming foam
APFO Ammonium perfluorooctanoate
ATSDR Agency for Toxic Substances and Disease Registry
CDC Center for Disease Control and Prevention
CDR Chemical Data Reporting
CERCLA Comprehensive Environmental Response, Compensation, and Liability Act
CFR Code of Federal Regulations
COP–9 9th Conference of Parties
DoD Department of Defense
DOE Department of Energy
DNA Deoxyribonucleic acid
EA Economic Analysis
EALs Environmental action levels
ECF Electrochemical fluorination
EJ Environmental justice
EPA Environmental Protection Agency
EPCRA Emergency Planning and Community Right-to-Know Act
EU European Union
FAA Federal Aviation Administration
FDA Food and Drug Administration
FR Federal Register
FSANZ Food Standards Australia New Zealand
IARC International Agency for Research of Cancer
ICR Information Collection Request
ILs Initiation levels
LEPC Local Emergency Planning Committee
LHA Lifetime health advisories
MAC Maximum acceptable concentration
MCL Maximum contaminant level
MDH Minnesota Department of Health
mg/kg milligram per kilogram
mg/kg/day milligram per kilogram per day
MRL Minimal risk level
MSC Medium-specific concentration
NAICS North American Industrial Classification System
NCP National Oil and Hazardous Substances Pollution Contingency Plan
ng/g nanograms per gram
ng/L nanograms per liter
NHANES National Health and Nutrition Examination Survey
NJDEP New Jersey Department of Environmental Protection
NPL National Priorities List
NRC National Response Center
OMB Office of Management and Budget
PADEP Pennsylvania Department of Environmental Protection
PBI Proprietary business information
PCBs Polychlorinated biphenyls
PCL Protective concentration level
PER Perimeter Well Study
PFAS Per- and polyfluoroalkyl substances
PFBS Perfluorobutanesulfonic acid
PFDA Perfluorodecanoic acid
PFHpA Perfluoroheptanoic acid
PFHxA Perfluorohexanoic acid
PFHxS Perfluorohexanesulfonic acid
PFNA Perfluorononanoic acid
PFOA Perfluorooctanoic acid
PFOS Perfluorooctanesulfonic acid
PFOSA Perfluorooctanesulfonamide
pg/m^3 picogram per cubic meter
PHGs Public health goals
POSF Perfluorooctanesulfonyl fluoride
ppt parts per trillion
PRG Preliminary remediation goal
PWS Public water system
RAGs Remedial action guidelines
RCRA Resource Conservation and Recovery Act
REACH Registration Evaluation, Authorisation and Restriction of Chemicals
RFA Regulatory Flexibility Act
RfD Reference dose
RIDEM Rhode Island Department of Environmental Management
RML Regional removal management level
RQ Reportable quantity
RSL Regional screening level
SAB Science Advisory Board
SALs State action levels
SDWA Safe Drinking Water Act SERC State Emergency Response Commission
SNURs Significant New Use Rules
TDI Tolerable daily intake
TEPC Tribal Emergency Planning Committee
TERC Tribal Emergency Response Commission
TRI Toxic Release Inventory
TSCA Toxic Substances Control Act
UCMR Unregulated Contaminant Monitoring Rule
UK United Kingdom
UMRA Unfunded Mandates Reform Act

UNEP United Nations Environment Programme
U.S. United States
U.S.C. United States Code
WQCC Water Quality Control Commission
WWTP Wastewater treatment plant

Table of Contents

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2019–0341, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Propriety Business Information (PBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud or other file sharing system). For additional submission methods, the full EPA public comment policy, information about PBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to monitor information carefully and continuously from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

II. Does this action apply to me?

The purpose of this proposed rulemaking is to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances under CERCLA section 102(a). Upon designation, any person in charge of a vessel or an offshore or onshore facility, as soon as they have knowledge of any release of such substances at or above the reportable quantity (RQ) must immediately report such releases to the Federal, state, tribal and local authorities (CERCLA section 103(a), Emergency Planning and Community Right-to-Know Act (EPCRA) section 304). The RQ for these designations is 1 pound or more in a 24-hour period. Once EPA has collected more data on the size of releases and the resulting risks to human health and the environment, the Agency may consider issuing a regulation adjusting the reportable quantities for these substances.

The five broad categories of entities potentially affected by this action include: (1) PFOA and/or PFOS manufacturers (including importers and importers of articles); (2) PFOA and/or PFOS processors; (3) manufacturers of products containing PFOA and/or PFOS; (4) downstream product manufacturers and users of PFOA and/or PFOS products; and (5) waste management and wastewater treatment facilities. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this action applies to them. Potentially affected entities may include:

NAICS code	List of potentially affected U.S. industrial entities
488119	Aviation operations.
314110	Carpet manufacturers.
811192	Car washes.
325	Chemical manufacturing.
332813	Chrome electroplating, anodizing, and etching services.
325510	Coatings, paints, and varnish manufacturers.
325998	Firefighting foam manufacturers.
562212	Landfills.
339112	Medical Devices.
922160	Municipal fire departments and firefighting training centers, including Federal agencies that use, trained with, and tested firefighting foams.
322121 and 322130	Paper mills.
325320	Pesticides and Insecticides.

NAICS code	List of potentially affected U.S. industrial entities
324	Petroleum and coal product manufacturing.
324110 and 424710	Petroleum refineries and terminals.
352992	Photographic film manufacturers.
325612	Polish, wax, and cleaning product manufacturers.
325211	Polymer manufacturers.
323111 and 325910	Printing facilities where inks are used in photolithography.
313210, 313220, 313230, 313240, and 313320.	Textile mills (textiles and upholstery).
562	Waste management and remediation services.
221320	Wastewater treatment plants.

III. General Information

A. Executive Summary

EPA is proposing to designate two per- and polyfluoroalkyl substances (PFAS)—specifically PFOA and PFOS including their salts and structural isomers [1] as hazardous substances because evidence indicates that these chemicals may present substantial danger to public health or welfare or the environment when released into the environment. All references to PFOA and PFOS in this notice are meant to include their salts and linear and branched structural isomers. Linear and branched structural isomers of PFOA and PFOS maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain.

PFOA and PFOS have historically been found in or used in making a wide range of consumer products including carpets, clothing, fabrics for furniture, and packaging for food and cookware that are resistant to water, grease or stains. They are also used for firefighting at airfields and in a number of industrial processes. PFOA and PFOS are persistent and mobile in the environment, and exposure can lead to adverse human health effects, including high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney for PFOA, liver and thyroid cancer for PFOS). In June 2022, EPA released interim updated health advisories for PFOA and PFOS based on human epidemiology studies in populations exposed to these chemicals. Based on the new data and EPA's draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt).

EPA believes the totality of evidence about PFOA and PFOS described here demonstrates that they can pose substantial danger to public health or welfare or the environment. This level of evidence is more than sufficient to satisfy the CERCLA section 102(a) standard. EPA believes that this amount and type of evidence exceeds the minimum required under CERCLA section 102(a).

PFOA and PFOS are common contaminants in the environment because of their release into the environment and their resistance to degradation. PFAS generally, and PFOA and PFOS specifically, are sometimes referred to as ''forever'' chemicals because their strong carbon-fluorine bonds cause PFOA and PFOS to be extremely resistant to degradation in the environment. PFAS are found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean. PFAS are also found in the artic snow and air.[2]

PFOA and PFOS are found worldwide in many environmental media and in wildlife. For example:

- PFOA and PFOS are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States.
- PFOA and PFOS have been detected in surface and subsurface soils.
- PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. PFOA and PFOS have been found in wild and domestic animals such as fish, shellfish, alligators, deer and avian eggs.

Environmental sources can include industrial, and inadvertent municipal and agricultural discharges of PFOA and PFOS directly. PFOA and PFOS precursors can be converted to PFOA and PFOS, respectively, by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. PFOA and PFOS that are deposited or created by the degradation of their precursors in industrial and consumer waste, in a landfill without environmental controls, can discharge via leachates, groundwater pollution/migration and atmospheric releases.

The principal worldwide manufacturers of PFOA and PFOS and related chemicals phased out their production in the early 2000's although PFOA and PFOS may still be produced domestically for certain uses and by international companies that export treated products to the United States. Environmental contamination and resulting human exposure to PFOA and PFOS are anticipated to continue for the foreseeable future due to its environmental persistence, formation from precursor compounds, continued production by international manufacturers and possible domestic production, and as a result of the large legacy production in the United States. Although PFOA and PFOS levels have been decreasing in human serum samples since the phase out, they are still detected in a high percentage of the U.S. population.[3]

The adverse human health effects, mobility, persistence, prevalence, and other factors related to these PFAS combine to support EPA's proposed finding that PFOA and PFOS, when released into the environment may present substantial danger to the public health or welfare or the environment and, as a result, warrant designation as CERCLA hazardous substances.

The potential dangers posed by PFOA and PFOS specifically, and more generally by PFAS, have been recognized by numerous Federal, state, and international governmental entities that have taken a wide variety of actions to address these dangers to public health and welfare and the

[1] All references to PFOA and PFOS in this notice are meant to include their salts and linear and branched structural isomers. Linear and branched structural isomers of PFOA and PFOS maintain the carboxylic acid and sulfonic acid functional groups, respectively, but have different arrangements of the carbon atoms in the fluorinated carbon chain.

[2] Scientific Reports (2016) Natural Poly-/perfluoroalkyl Substances in Air and Snow from the Artic *https://www.nature.com/articles/srep08912*.

[3] CDC. (2021). National Health and Nutrition Examination Survey: NHANES questionnaires, datasets, and related documentation. Centers for Disease Control and Prevention. *https://wwwn.cdc.gov/nchs/nhanes/Default.aspx*.

environment. For example, the Department of Defense has been providing alternative drinking water to local residents near military bases with elevated PFOA and PFOS levels from DoD activities. Many states, including California, Michigan, and Vermont have drinking water standards for PFOA and PFOS. And numerous international bodies, such as the European Union, and individual countries, such as Australia, China, and Canada, have taken measures to address PFOA and PFOS. Designating PFOA and PFOS as hazardous substances will add to the set of tools already available under CERCLA to protect the public health and welfare and the environment.

If finalized, the direct effects of this proposed CERCLA designation would include requiring that any person in charge of a vessel or facility report releases of PFOA and PFOS of one pound or more within a 24-hour period. This would give the Agency, state, Tribal, and local governments, and the public a better understanding of where releases occur and the quantities involved.

In addition, when selling or transferring Federally-owned real property, Federal agencies would be required to meet all of the property transfer requirements in CERCLA section 120(h), including providing notice when any hazardous substance ''was stored for one year or more, known to have been released, or disposed of'' and providing a covenant warranting that ''all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States.'' This would ensure that any entity receiving Federal land is informed of the presence of PFOA or PFOS, and that these substances will be addressed as required under CERCLA. There would also be an obligation for DOT to list and regulate PFOA and PFOS as hazardous materials under the Hazardous Materials Transportation Act (HMTA) (see CERCLA Section 306(a)).

In addition to those direct effects, if finalized, these designations would provide some additional tools that the government and others could use to address PFOA/PFOS contamination and, thus, could facilitate an increase in the pace of cleanups of PFOA/PFOS contaminated sites. Furthermore, there will likely be additional response actions beyond those that are simply undertaken before designating PFOA/PFOS a hazardous substance, although the quantity of such an increase is indeterminable. The Federal government is already authorized to cleanup PFOA/PFOS contamination under some circumstances, including when it finds that a release may present an imminent and substantial danger to public health or welfare. A faster pace of cleanups would provide public health protection for affected communities sooner and could reduce the cost of individual cleanups (generally, the sooner contamination is addressed, the less it spreads and the smaller the area that needs to be cleaned). The indirect, downstream effects of these designations could include the following:

• EPA and other agencies exercising delegated CERCLA authority could respond to PFOA and PFOS releases and threatened releases without making the imminent and substantial danger finding that is required for responses now.

• EPA and delegated agencies could require potentially responsible parties to address PFOA or PFOS releases that pose an imminent and substantial endangerment to public health or welfare or the environment.

• EPA and delegated agencies could recover PFOA and PFOS cleanup costs from potentially responsible parties, to facilitate having polluters and other potentially responsible parties, rather than taxpayers, pay for these cleanups.

• Private parties that conduct cleanups that are consistent with the National Oil and Hazardous Substances Contingency Plan (NCP) could also recover PFOA and PFOS cleanup costs from potentially responsible parties.

These impacts from the proposed rule will result in meaningful public health benefits, including by increasing transparency around PFOA/PFOS releases and offering additional tools that EPA and other government agencies could use to conduct faster cleanups at contaminated sites.[4]

In addition to this action, in 2022, the EPA will be developing an advance notice of proposed rulemaking seeking comments and data to assist in the development of potential future regulations pertaining to other PFAS designation as hazardous substances under CERCLA.

[4] See the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* in the rulemaking docket for a discussion of indirect benefits and costs.

B. What are PFOA and PFOS, and how have they been used?

PFAS, including PFOA and PFOS, are human-made chemicals that have been used in industry and consumer products since the 1940s because of their useful properties, including their resistance to water, grease, and stains. In terms of their chemistry, they exist as linear and branched isomers, depending on the methods by which they are produced. Both PFOA and PFOS have been manufactured in numerous salt forms.[5] In considering toxicity and fate and transport processes, the salts are deemed the same as the commonly referenced acid versions because, once added to water, the salts dissociate to the component ions (there are two ions, the cation and the anion). Hence, if any of the salt or acid forms of PFOA or PFOS are released into the environment, the anionic form will generally be found in environmental media; all references to PFOA and PFOS in this preamble are meant to include all salts and structural isomers.[6]

PFOA and PFOS have been produced within the United States (U.S.)[7] as well as imported. Although PFOA and PFOS production may be ending in the United States, their continued use in certain applications and persistence in the environment means that their historical production and use will continue to be a concern in the future.

PFOA and PFOS can also be formed by chemical or biological degradation from a large group of related PFAS (*i.e.,* precursor compounds).[8] [9] The nature of PFOA and PFOS (*i.e.,* reactivity as both a base and acid) has led to their use in a variety of manufactured goods, industrial applications, or the environment, including the following:

• Food packaging and preparation, including PFAS-containing materials

[5] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[6] Ibid.

[7] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237*.

[8] Ibid.

[9] UNEP. (2006). Report of the Persistent Organic Pollutants Review Committee on the work of its second meeting. Addendum: Risk profile on perfluorooctane sulfonate. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.2/17/Add.5). United Nations Environment Programme. *https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC2/POPRC2ReportandDecisions/tabid/349/Default.aspx*.

(*e.g.,* sandwich wrappers, and other paper and paperboard food packaging) and processing equipment that uses PFAS. This can lead to migration of PFAS into food that contacts such surfaces.

- Commercial household products, including stain- and water-repellent fabrics, nonstick products, polishes, waxes, paints, and cleaning products.
- Certain firefighting foams. PFAS can be found in groundwater and surface water at airports, military bases and other facilities where PFAS-containing firefighting foam was used for training, incident response, or where foam was stored.
- Manufacturing and production, including chrome plating, electronics manufacturing, textile manufacturing or oil recovery.
- Drinking water, typically because of localized contamination associated with a specific facility (*e.g.,* manufacturer, landfill, wastewater treatment plant, firefighter training facility).
- Living organisms, including plants, animals and humans due to the above-mentioned sources.
- Plating processes, such as a wetting agent/fume suppressant.
- Non-stick cookware and food processing equipment.
- Processing aids in fluoropolymer production.
- Processing aids in textile coating applications.
- Insecticides.
- Certain types of adhesives.
- Cleaning products, such as carpet cleaners, auto washes and electronics.
- Coating products, paints, varnishes and inks.
- Surfactants for oil extraction and mining.
- Photo lithography, photographic coatings
- Hydraulic fluids for aviation.[10 11]
- Certain explosives and pyrotechnics as binders and oxidizers.

The most common processes for making fluorinated chemicals, including PFOA and PFOS, are electrochemical fluorination (ECF) and telomerization. Production sites that produced PFAS by means of ECF were located in the U.S., including Decatur, Alabama. International production sites include Belgium (Zwijndrecht near Antwerp) and Italy (Miteni in Vicenza)).

Although PFOA and PFOS production may be ending in the United States, their continued use in certain applications and persistence in the environment means that their historical production and use will continue to be a concern in the future.

Domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program. Small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (see 40 Code of Federal Regulations (CFR) 721.9582).[12] The EPA Chemical Data Reporting (CDR) rule under the Toxic Substance Control Act (TSCA) requires manufacturers (including importers) to report certain data about chemicals in commerce in the United States, including information on PFOA and PFOS (subject to a 2,500 pound reporting threshold at a single site). The last time PFOA and PFOS manufacturing information was reported to EPA pursuant to CDR was in 2013 and 2002, respectively. However, Toxics Release Inventory (TRI) data for 2020 shows that small amounts of PFOA and PFOS continue to be released into the environment. Pursuant to TRI reporting requirements, facilities in regulated industry sectors must report annually on releases and other waste management of certain listed toxic chemicals that they manufacture, process, or otherwise use above certain threshold quantities (100 pounds for PFOA and PFOS).

C. What action is the Agency taking?

The EPA is proposing to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances under section 102(a) of CERCLA.

The designation of PFOA and PFOS, including their salts and structural isomers, as hazardous substances, if finalized, would result in a default RQ of one pound pursuant to CERCLA section 102. CERCLA section 103(a) requires any person in charge of a vessel or facility, as soon as they have knowledge of any release[13] (other than a federally permitted release) of a hazardous substance from such vessel or facility in quantities equal to or greater than the RQ (one pound) or more in a 24-hour period, to immediately notify the National Response Center (NRC) of such a release. The reporting requirements are further codified in 40 CFR 302.6(a). Section 304 of EPCRA (42 (United States Code) U.S.C. 11004) also requires facility owners or operators to immediately notify their community emergency coordinator for local emergency planning committee (LEPC) (or Tribal emergency planning committee (TEPC)), if established, for any area likely to be affected by the release and to notify the State Emergency Response Commission (SERC) (or Tribal Emergency Response Commission (TERC)) of any state or Tribal region likely to be affected by the release. EPCRA section 304 also requires facilities to submit a follow-up written report to their SERC (or TERC) and the LEPC (or TEPC) as soon as practicable after the release. EPA published a guidance on July 13, 2010 (75 **Federal Register** (FR) 39852) defining the phrase, ''as soon as practicable'' to be 30 days after a release. (Note: Some states or Tribal Nations provide less than 30 days for submitting a follow-up report.) EPCRA section 304 requirements are codified in 40 CFR 355.30 to 355.43.[14]

In addition, when Federal agencies sell or transfer real property they must provide notice of the presence of hazardous substances in certain circumstances as required by CERCLA section 120(h). Furthermore, in certain circumstances, CERCLA 120(h) requires Federal agencies to provide a covenant warranting that ''all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States.''

While these are the only direct and automatic consequences of designating PFOA and PFOS hazardous substances for purposes of CERCLA, there are other, indirect impacts described above that should facilitate cleanups and reduce

[10] U.S. EPA. (2014). Certain perfluoroalkyl sulfonates. U.S. Environmental Protection Agency. Code of Federal Regulations. 40 CFR 721.9582. *https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-sec721-9582.pdf.*

[11] Glüge, J; Scheringer, M; Cousins, IT; DeWitt, JC; Goldenman, G; Herzke, D; Lohmann, R; Ng, CA; Trier, X; Wang, Z. (2020). An overview of the uses of per-and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts 22: 2345–2373. *https://www.ncbi.nlm.nih.gov/pubmed/33125022.*

[12] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[13] *See* Office of Regulatory Enforcement, EPA, *Enforcement Response Policy for Sections 304, 311 and 312 of EPCRA and Section 103 of CERCLA* at 12 (Sept. 30, 1999), *available at https://www.epa.gov/enforcement/enforcement-response-policy-epcra-sections-304-311-312-and-cercla-section-103. See also https://www.epa.gov/epcra/definition-immediate-epcra-and-cercla-release-notification.*

[14] For additional information on release reporting requirements, see *https://www.epa.gov/faqs/search/topics/emergency-planning-and-community-right-know-304487/topics/release-notification-epcra-304cercla-103-30450.*

human and environmental exposure to these hazardous chemicals.

IV. Legal Authority

A. Background

CERCLA was enacted to promote the timely cleanup of contaminated sites and to ensure that parties responsible for the contamination bear the costs of such cleanups. CERCLA provides the Federal government with the authority to respond to releases or threatened releases of hazardous substances, and pollutants and contaminants in order to protect public health, welfare, and the environment. The statute confers considerable discretion upon the EPA in its exercise of these authorities. Other than the reporting requirements in the statute, CERCLA is not a traditional regulatory statute that prospectively regulates behavior; rather it is remedial in nature, generally designed to address contamination on a site-specific basis.

CERCLA required a significant update to the NCP, which provides the ''procedures and standards for responding to releases of hazardous substances, pollutants, and contaminants . . . .'' CERCLA section 105(a). The NCP is the blueprint for all aspects of the cleanup process, from the discovery of releases of contaminants, to responding to releases or threatened releases that require prompt response, and to prioritizing and developing longer-term remedial actions.

Once a Federal agency learns of a release or potential threat of a release of a hazardous substance, pollutant and/or contaminant, CERCLA authorizes response in one of three ways: by determining no action at the Federal level is warranted; by undertaking a removal action (if the situation presents a more immediate threat); or by assessing the relative risk of the release to other releases via the NPL listing process that is the first step towards a longer-term remedial action. Superfund cleanups typically begin with a preliminary assessment/site inspection, which includes reviews of historical information and site visits to evaluate the potential for a release of hazardous substances. EPA determines whether the site poses a threat to people and the environment and whether hazards need to be addressed immediately or additional site information will be collected. Federal entities other than EPA that respond to releases or threatened releases of hazardous substances, pollutants, or contaminants at Federal sites must similarly act consistent with CERCLA and the NCP. Finally, private parties responding to a release or threatened release at their facility must act consistent with CERCLA and the NCP in order to maintain CERCLA claims for recovery of response costs.

The nature of the subsequent response action depends upon the site-specific circumstances. Short-term ''removals'' are response actions that EPA and other Federal agencies may take to address releases or threatened releases requiring prompt action and are limited in cost and duration unless specific criteria are met. Long-term ''remedial'' actions permanently and significantly reduce the risks associated with releases or threats of releases that are serious and are typically associated with chronic exposures, but not immediately life-threatening. EPA can only conduct remedial actions at sites listed on EPA's National Priorities List (NPL). Additions to the NPL undergo notice-and-comment rulemaking. The NPL sites are among the worst hazardous substance sites identified by EPA. Only about 3% of the 53,400 assessed sites have been placed on the NPL. If a site is placed on the NPL, a Remedial Investigation/Feasibility Study is conducted to assess risks posed by releases of a hazardous substance, pollutant, or contaminant at the site by evaluating soil, surface water, ground water, and other media, and waste samples, and to analyze potential treatment methods or cleanup alternatives. EPA then summarizes those alternatives and offers its recommendation in a Proposed Plan, which undergoes a public comment process. The final decision on the cleanup is memorialized in a Record of Decision, which is accompanied by a responsiveness summary addressing the public comments. The specific details of the cleanup are then planned in the Remedial Design and finally carried out in the Remedial Action. Ultimately, the remedy must be one ''that is protective of human health and the environment, that is cost effective, and that utilizes permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable.'' CERCLA section 121(b)(1).

CERCLA provides authority for response actions to address releases of hazardous substances as well as releases of pollutants and contaminants. The authority conferred by CERCLA with regard to hazardous substances differs in a few respects from the authority with regard to pollutants and contaminants. With respect to *hazardous substances,* the Agency can conduct response actions if there is a release or threatened release without having to establish an imminent and substantial danger. In addition, the EPA can also recover costs from potentially responsible parties and require potentially responsible parties to conduct the cleanup themselves. CERCLA also authorizes persons (including private parties) that conduct cleanup activities that are consistent with the NCP to seek to recover cleanup costs from potentially responsible parties. With respect to releases or substantial threat of releases of *pollutants and contaminants,* EPA can respond if the Agency finds that the release or threat of release may present an imminent and substantial danger to the public health or welfare, and, generally, cannot require a private party to pay for or conduct the removal action.

Accordingly, CERCLA already provides significant authority to Federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants. Nonetheless, designating PFOA and PFOS as hazardous substances will likely increase the pace at which cleanups occur because it will allow the Federal government to require responsible private parties to address releases of PFOS and PFOA at sites without other ongoing cleanup activities, and allow the government and private parties to seek to recover cleanup costs from potentially responsible parties assuming relevant statutory criteria are met. As a result, risks from releases of PFOA and PFOS may be mitigated.

B. Explanation of Criteria for Designation Decisions

CERCLA section 101(14) sets out the definition of ''hazardous substance.'' There are two ways that a substance may be defined as a ''hazardous'' substance under CERCLA. The first is automatic where the substance is identified as hazardous or toxic pursuant to other specified environmental statutes (*e.g.,* chemicals listed as air toxics by Congress or EPA under section 112 of the Clean Air Act). The second is where the substance is designated as hazardous pursuant to CERCLA section 102. In this action, the Administrator is exercising his authority to designate under section 102.

1. Statutory Factors To Be Considered Under Section 102

The EPA Administrator is authorized under CERCLA section 102(a) to promulgate regulations designating as a hazardous substance:

(1) ''such elements, compounds, mixtures, solutions, and substances''

(2) ''which, when released into the environment''

(3) ''may present substantial danger''
(4) ''to the public health or welfare or the environment.''

The term ''hazardous substance'' is defined in section 101(14) of CERCLA primarily by reference to other environmental statutes and includes substances designated pursuant to CERCLA section 102. Pursuant to CERCLA section 101(14) the term hazardous substance means (A) any substances designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. 1321(b)(2)(A)], (B) any element, compound, mixture, solution, or substances designated pursuant to section 9602 of this title, (C) any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921], (but not including any waste the regulation of which under the Solid Waste Disposal Act {42 U.S.C. 6901 *et seq.*] has been suspended by Act of Congress). (D) any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act {33 U.S.C. 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. 7412], and (F) any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. 2606]. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under paragraphs (A) through (F) of this paragraph, and the term does not include natural gas, natural gas liquids, liquified natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas).

Because EPA has not exercised its authority under CERCLA section 102(a), it has not previously issued an interpretation of the standard for designating hazardous substances.

EPA proposes to interpret ''may present'' in the statutory language as indicating that Congress did not require certainty that the substance presents a substantial danger or require proof of actual harm. In assessing whether a substance, when released, may present ''substantial danger,'' [15] the EPA proposes to consider information such as the following: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance moves and degrades when in the environment (*i.e.,* environmental fate and transport). To further inform its decision about whether the statutory factors have been met, the Agency proposes to also consider other information that may be relevant when evaluating releases of the substance, such as the frequency, nature and geographic scope of releases of the substances. The Agency proposes to weigh this information to determine whether the substance, when released, may present a ''substantial danger.''

2. CERCLA Section 102(a) Precludes Consideration of Cost

Given the specific standard Congress established for determining whether a substance is hazardous (*i.e.,* whether it ''may present substantial danger to the public health or welfare or the environment''), EPA proposes to interpret the language of CERCLA section 102(a) as precluding the Agency from taking cost into account in designating hazardous substances. Congress did not list cost as a required or permissible factor, and none of the Congressionally-listed statutory factors encompass a consideration of cleanup costs. Moreover, as a matter of common sense and straightforward reading, determining whether something is ''hazardous'' does not naturally lend itself to considerations of cost. A substance is or is not hazardous based on scientific and technical considerations. Subsequent determinations of *whether and how to address* something hazardous may involve considerations of cost, as CERCLA does in the context of response actions, as discussed below.

a. Consistency With Case Law

Reading CERCLA as precluding consideration of costs in hazardous substance designations is consistent with relevant Supreme Court precedent on cost consideration in rulemaking decisions. CERCLA section 102(a) is similar to Clean Air Act section 109(b)(1),[16] which governs EPA's setting of national ambient air quality standards (NAAQS) and which the Supreme Court said precludes consideration of costs. *Whitman* v. *American Trucking,* 531 U.S. 457 (2001). In his majority opinion, Justice Scalia explained,

> The EPA, ''based on'' the information about health effects contained in the technical ''criteria'' documents compiled under section 108(a)(2), 42 U.S.C. 7408(a)(2), is to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an ''adequate'' margin of safety, and set the standard at that level. Nowhere are the costs of achieving such a standard made part of that initial calculation.

American Trucking, 531 U.S. at 465.

Similarly, CERCLA section 102(a) establishes a standard for designation that is tied exclusively to whether the release of a substance ''may present substantial danger to the public health or welfare or the environment.'' 42 U.S.C. 9602(a). Congress did not mention cost in this language that sets the standard for designation of hazardous substances.

Section 102(a)'s specific designation standard and its statutory context differentiate it from the broader statutory standard in Clean Air Act section 112(n)(1)(A), which the Supreme Court held requires EPA to consider costs in determining whether to regulate air toxic emissions from power plants in *Michigan* v. *EPA,* 576 U.S. 743 (2015). Clean Air Act section 112(n)(1)(A) states, in part,

> The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary after considering the results of the study required by this paragraph.

42 U.S.C. 7412(n)(1)(A). The Supreme Court explained that ''appropriate'' is a broad term that ''includes consideration of all the relevant factors'' and when read in the context of Clean Air Act section 112(n)(1)(A) requires ''at least some attention to cost.'' *Michigan,* 576 U.S., at 752. In particular, the Court pointed to a study that was required by

[15] The EPA notes that the ''substantial danger'' language in CERCLA section 102(a) is similar to language in other parts of CERCLA but is interpreted in a different manner due to the contexts in which the language appears. Those other provisions (*see, e.g.,* CERCLA sections 104, 105, 106, and 128) concern enforcement and response actions and apply to and require analyses of site-specific circumstances relevant to a particular facility or person, and to an event. By contrast, the statutory objectives associated with designating hazardous substances under CERCLA section 102(a) warrant a different implementation strategy because of its broader applicability and analytical requirements. The standard for CERCLA section 102(a) in this notice is based on the specific language and purpose of section 102(a) and does not affect EPA's interpretations of other CERCLA provisions. *See Utility Air Regulatory Group* v. *EPA,* 573 U.S. 302, 320 (2014) (finding that statutory terms, even those that are defined in the statute, ''may take on distinct characters from association with distinct statutory objects calling for different implementation strategies.'').

[16] ''National primary ambient air quality standards, prescribed under paragraph (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.'' 42 U.S.C. 7409(b)(1).

the same paragraph (*i.e.,* Clean Air Act section 112(n)(1)), and noted both that Congress required that this study address cost (among other factors), and that EPA said that study helped provide a ''framework'' for EPA's decision under Clean Air Act section 112(n)(1). Given this context, in interpreting the Clean Air Act section 112(n)(1)'s ''appropriate and necessary'' standard for triggering regulation of air toxics from power plants, the Court held that EPA must consider cost in deciding whether to regulate power plants.

The standard for designation in CERCLA section 102(a) is significantly more circumscribed than the standard at issue in *Michigan.* As noted above, in CERCLA section 102(a), Congress specified a public health and welfare and environment standard governing EPA's designation decisions that did not include cost. In these circumstances, *Michigan* acknowledged that:

> *American Trucking* thus establishes the modest principle that where the Clean Air Act expressly directs EPA to regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway.

Id. at 755–56. Because CERCLA section 102(a) specifies the standard that EPA is to use, and it wholly relates to danger to public health, welfare, or the environment, cost should not be read in as an additional consideration. Furthermore, CERCLA section 102(a) is lacking provisions that indicate Congressional intent to take cost into account—unlike CAA section 112(n)(1), which had cost elements in provisions that the Court and EPA said were relevant to interpreting the ''appropriate and necessary'' standard.

CERCLA section 102(a) does use the word ''appropriate'' (the Administrator shall ''promulgate and revise as may be appropriate'' regulations designating hazardous substances), but significantly, the word ''appropriate'' is not used in the context of what EPA should consider when assessing whether a substance is hazardous. And as the Michigan Court noted, ''appropriate and necessary'' does not always encompass cost, context matters. See *Michigan,* 576 U.S. at 752. Under CAA section 112(n)(1), the substantive standard is nothing more than whether regulation is ''appropriate and necessary'' and, to the extent Congress provided a contextual indication about the meaning of that capacious phrase, it indicated that cost was relevant. In contrast, under CERCLA section 102(a), the Administrator is to promulgate and revise as may be appropriate regulations that accomplish the statutory goal of designating hazardous substances—and the guidance Congress provided was that the Administrator should look to specific criteria that do not include cost. Thus, EPA's authority to designate a substance as hazardous is tied solely to a finding that, when released, the substance may present a substantial danger to public health or welfare or the environment.

In addition, the Court in both *American Trucking* and *Michigan,* looked to the overall statutory scheme to determine whether cost should be considered as part of the Agency's determination. The role of a hazardous substance designation in the overall structure of CERCLA is much closer to the role of a national ambient air quality standard in the overall structure of the NAAQS program than it is to the role of the appropriate and necessary finding in regulating air toxic emissions from power plants.

Under CERCLA, the only automatic, private party obligation that flows from designation as a CERCLA hazardous substance under section 102(a) is the obligation to report releases (a relatively small cost). As discussed above, designation does not lead automatically to any response action obligations. CERCLA response actions, which include investigations of hazardous substance releases and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific actions.[17] EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment (such as on the remedial action objectives and the consideration of remedial alternatives); and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach.

For both the hazardous substance designation in CERCLA and the setting of a NAAQS, there are later steps in the program where cost can be taken into account before specific requirements are imposed on entities subject to the programs. In contrast, in *Michigan,* the Court seemed to weigh heavily the fact that, if regulations are ''appropriate and necessary'' under section 112(n)(1)(A), then, without regard to cost, ''the Agency must promulgate certain minimum emission regulations, known as floor standards.'' *Michigan,* 576 U.S., at 748.

Furthermore, the designation of a hazardous substance under CERCLA section 102(a) in some cases does not create *new* costs, but rather allows costs to be shifted from the taxpayer to parties responsible for pollution under CERCLA. Even in those circumstances, where the government is able to transfer costs, a private party's ability to pay response costs is taken into account under the statute and in EPA's implementation of the statute.[18]

The interpretation that section 102(a) precludes the consideration of cost in designation decisions is also supported by the Court of Appeals for the D.C. Circuit. In *Utility Solid Waste Activities Group* v. *EPA,* 901 F.3d 414 (D.C. Cir. 2018), the D.C. Circuit, relying on *Michigan* and *American Trucking,* upheld EPA's decision that it should not have considered cost in establishing requirements under the Resource Conservation and Recovery Act (RCRA) for disposing of coal combustion residuals because the statutory standard only addresses ''adverse effects on health or the environment'' without mentioning costs or including other language that could encompass cost.

Based in part on Supreme Court decisions addressing statutory interpretation and the D.C. Circuit's application of those decisions, EPA proposes to interpret CERCLA section 102(a) as precluding consideration of costs in hazardous substance designations.

b. Consistency With Statutory Structure

The way CERCLA initially established the list of hazardous substances shows that Congress did not intend for costs to be considered in designation decisions. As noted above, CERCLA offers two ways for a substance to be designated as hazardous. One is a finding pursuant to CERCLA section 102. Another is the list of other statutory provisions in CERCLA section 101(14) that identify hazardous and toxic substances. In that section, Congress directed that the definition of

[17] As noted below in section IV.B.2.c. and the *Economic Assessment,* the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage. The uncertainty at this stage, when contrasted with the greater certainty and explicit consideration of costs during the later cleanup selection process, further supports EPA's proposed interpretation that CERCLA precludes consideration of costs when designating a hazardous substance.

[18] *See* Memorandum from Susan Shinkman, Director, Office of Civil Enforcement, and Cynthia Mackey, Director, Office of Site Remediation Enforcement, US EPA (June 29, 2015) (Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action); Memorandum from Barry Breen, Director, Office of Site Remediation Enforcement, US EPA (Sep. 30, 1997) (General Policy on Superfund Ability to Pay Determinations).

Federal Register / Vol. 87, No. 171 / Tuesday, September 6, 2022 / Proposed Rules 54423

''hazardous substance'' includes all substances identified as hazardous or toxic by Congress or EPA under other specified environmental statutes:

- Clean Water Act section 311(b)(2)(A) hazardous substances;
- Resource Conservation and Recovery Act section 3001 hazardous wastes;
- Clean Water Act section 307(a) toxic pollutants;
- Clean Air Act section 112 hazardous air pollutants; and
- Toxic Substances Control Act section 7 imminently hazardous chemical.

When EPA adds a substance or chemical for regulation under any of those other statutory provisions, it also becomes a CERCLA hazardous substance—without considering the resulting costs under CERCLA.

In addition to the other statutory provisions listed above, CERCLA section 101(14) also includes CERCLA section 102(a), which suggests it should be interpreted in a manner similar to the other authorities on the list. Under the other statutory provisions, that program's compliance costs are not considered a factor or criteria in making listing decisions,[19] and the Agency proposes to interpret CERCLA section 102(a) as similarly excluding consideration of cost.

c. Costs

While EPA proposes to interpret CERCLA section 102(a) as excluding consideration of cost in a designation decision, the Agency is soliciting comment on that interpretation and, if costs should be considered, how they should be considered. See section IV.B.2.d. below.

EPA has estimated parties' potential direct costs associated with this designation decision (from reporting releases); they are relatively small and would not impede a designation decision even if the Agency were required to consider costs.

It is impractical, however, to quantitatively assess the indirect costs (for response actions) associated with a designation decision because of the uncertainty about such costs at this early stage in in the process. However, a qualitative discussion of indirect costs and benefits, as well as details explaining the impracticality of quantitative estimates are contained in the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances.*[20] Possible indirect costs could arise from an increased number of sites identified, assessed and/or remediated, and from associated research and development. In addition, economic costs could be offset by savings from faster and more efficient response actions. Possible indirect benefits could include reduced health effects such as cancer, immunological problems, high cholesterol, and thyroid disorders resulting from earlier and greater numbers of response actions due to release reporting, and application of enhanced response authority.

A designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs.

Response actions are contingent, discretionary, and site-specific decisions made after a hazardous substance release or threatened release. They are contingent upon a series of separate discretionary actions and meeting certain statutory and regulatory requirements, as explained above. In addition, future discretionary decisions about cleanup and response are difficult to quantify due to numerous, significant uncertainties such as: (1) How many sites have PFOA or PFOS contamination at a level that warrants a cleanup action; (2) the extent and type of PFOA and PFOS contamination at/near sites; (3) the extent and type of other contamination at/near sites; (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and (5) the cleanup level required for these substances.

d. Request for Comment

EPA proposes to interpret CERCLA section 102(a) as prohibiting the Agency from considering cost as part of its decision to designate hazardous substances, EPA is taking comment on its approach to the consideration of costs, including: (1) Whether CERCLA section 102(a) precludes, allows, or requires consideration of cost in designation decisions, and, if so, (2) which costs and benefits of those discussed in the EA should be considered, (3) whether additional benefits and costs not identified in the EA should be considered, (4) if indirect benefits and costs are considered, how they should be assessed in light of the discretion and uncertainties described above, (5) how benefits and costs could be incorporated into the designation decision, and (6) whether designation would be justified if costs were to be considered in the Agency's designation decision. In addition, the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* includes requests for comments on several topics related to indirect costs that EPA does not currently have robust information about. Please see Section ES–5 of the *Economic Assessment* for specific details.

V. Designation of PFOA, PFOS, and Their Salts and Structural Isomers as Hazardous Substances

A. Introduction

The EPA is proposing to designate PFOA and PFOS as hazardous substances because significant evidence indicates that they satisfy the statutory criteria set forth in CERCLA section 102(a):

(1) They are ''substances'' as described in section IV.B.;

(2) They may be ''released into the environment'' as described in section IV.B.;

(3) They may present substantial danger as described in section V; and

(4) That danger is ''to the public health or welfare or the environment'' as described in section V.

While EPA acknowledges that the science regarding PFOA and PFOS human health and environmental effects is still evolving, a significant body of scientific evidence shows that PFOA and PFOS are persistent and mobile in the environment, and that exposure to PFOA and PFOS may lead to adverse human health effects. Assessments conducted by EPA, other Federal, state, Tribal and international agencies, academia, non-profit organizations and the private sector support the conclusion that PFOA and PFOS warrant a hazardous substance designation. This conclusion is based on the factors considered by EPA in this proposal, which, as noted above, included the potential human health or environmental hazards associated with exposure to PFOA and PFOS and the environmental fate and transport of PFOA and PFOS. The evidence for concern about PFOA and PFOS includes:

- Chemical/Physical Characteristics
- Toxicity and Toxicokinetics

[19] *See, e.g.,* 42 U.S.C. 6921(a) (RCRA section 3001(a)); 42 U.S.C. 7412(b)(2) (Clean Air Act section 112(b)(2).

[20] U.S. EPA (2022) Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances.

• Environmental Prevalence

Each of the above evidence categories are discussed in more detail below. PFOA and PFOS hazardous substance designation would be consistent with and supportive of many other actions taken by EPA, other Federal agencies, states, Tribal Nations and international bodies. These entities have set PFOA and PFOS benchmarks and standards and have undertaken PFOA- and PFOS-based regulatory activities and enforcement actions. Details are provided below.

B. What is the evidence for designation of PFOA and PFOS as hazardous substances?

A significant collection of evidence and actions support designating PFOA and PFOS as hazardous substances under CERCLA section 102(a). EPA is proposing that, when released into the environment, PFOA and PFOS may present substantial danger to the public health or welfare or the environment. What follows are brief summaries and not a comprehensive review of the available literature.

1. Chemical/Physical Characteristics

PFOA and PFOS are persistent chemicals that bioaccumulate, and exposure to PFOA and PFOS may cause adverse human health effects. PFOA and PFOS are distinctive from many other bioaccumulative chemicals because their water-solubility allows them to migrate readily from soil to groundwater. If PFOA and PFOS are released into the environment, they can contaminate surface water and groundwater used as drinking water sources and persist for long periods of time, thereby posing a direct threat to human health and the environment.

PFOA is comprised of eight carbons, seven of which are fully fluorinated, and the eighth carbon is part of a carboxylic acid group. PFOA is considered a surfactant (*i.e.,* a substance that tends to reduce the surface tension of a liquid in which it is dissolved) due to its chemical structure consisting of a hydrophobic perfluorinated alkyl ''tail group'' and a hydrophilic carboxylate ''head group''.[21] [22] As a result of the head group, PFOA is water soluble, which contributes to its tendency to be found in groundwater.

PFOA is produced and used mainly as ammonium perfluorooctanoate (APFO), a salt of PFOA, that may include both linear and branched isomers. APFO's isomeric composition depends on the manufacturing processes used. The APFO that is produced through the perfluorooctyl iodide oxidation process, commonly called telomerization, is >99 percent linear, and the APFO that is produced by the ECF process is >70 percent linear with the remaining <30 percent a mixture of branched isomers.[23] [24] As a result, there are different PFOA structural isomers that may be released and found in the environment. Analytical chemistry methods used to detect and measure PFOA may measure the different isomers separately.

PFOS has a fully fluorinated eight-carbon linear or branched tail, with a hydrophilic sulfonate functional head group attached to the carbon tail. PFOS is manufactured from perfluorooctanesulfonyl fluoride (POSF), which is produced through ECF. This process results in linear and branched isomers of PFOS.[25] PFOS is often produced as its potassium salt. Like PFOA, PFOS is water soluble, which is why it can be found in groundwater.

As noted above, PFOA and PFOS contain carbon atoms bonded to fluorine atoms. These carbon-fluorine bonds are strong, causing PFOA and PFOS to be extremely resistant to degradation in the environment (including biodegradation, photolysis and hydrolysis) and, thus, likely to persist for long periods of time.[26] [27]

These chemical and physical characteristics of PFOA and PFOS, when viewed in combination with the information that follows, supports this proposed designation of these chemicals as CERCLA hazardous substances.

2. Toxicity and Toxicokinetics

Exposure to PFOA and PFOS is associated with a variety of adverse human health effects. Human studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, the cardiovascular system, human development (*e.g.,* decreased birth weight), and cancer. EPA continues to conduct extensive evaluations of human epidemiological and experimental animal study data to support the development of a PFAS National Primary Drinking Water Regulation. In November 2021, EPA released draft updated health effects analyses for PFOA and PFOS; these analyses are undergoing Science Advisory Board (SAB) review. EPA evaluated over 400 peer-reviewed studies published since 2016 and used new approaches, tools, and models to identify and evaluate the information. Based on the new data and draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 Health Advisories for PFOA and PFOS (70 ppt).

The following discussion is based on information and conclusions from the EPA 2016 Health Effects Support Documents for PFOA[28] and PFOS[29] and other published peer reviewed science. The weight of scientific evidence presented in the Health Effects Support Documents for PFOA[30] and

[21] ChEBI. (2017). ChEBI:35549—perfluorooctanoic acid. Chemical Entities of Biological Interest. European Molecular Biology Laboratory, European Bioinformatics Institute. *https://www.ebi.ac.uk/chebi/searchId.do?chebiId=CHEBI:35549.*

[22] Lindstrom, AB; Strynar, MJ; Libelo, EL. (2011). Polyfluorinated compounds: past, present, and future. Environ Sci Technol 45: 7954–7961. *https://www.ncbi.nlm.nih.gov/pubmed/21866930.*

[23] European Commission. (2015). Analysis of the risks arising from the industrial use of perfluorooctanoic acid (PFOA) and ammonium perfluorooctonate (APFO) and from their use in consumer articles. Evaluation and risk reduction measures for potential restrictions on the manufacture, placing on the market and use of PFOA and APFO. (TOX08.7049). European Commission, Enterprise and Industry Directorate—General. *https://ec.europa.eu/docsroom/documents/13037/attachments/1/translations/en/renditions/pdf.*

[24] Buck, RC; Franklin, J; Berger, U; Conder, JM; Cousins, IT; de Voogt, P; Jensen, AA; Kannan, K; Mabury, SA; van Leeuwen, SP. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integr Environ Assess Manag 7: 513–541. *https://www.ncbi.nlm.nih.gov/pubmed/21793199.*

[25] OECD. (2002). Hazard assessment of perfluorooctane sulfonate (PFOS) and its salts. Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, Co-operation on Existing Chemicals. (ENV/JM/RD(2002)17/FINAL. JT00135607). Organisation for Economic Co-operation and Development. *https://www.oecd.org/env/ehs/risk-assessment/2382880.pdf.*

[26] U.S. EPA. (2016). Drinking water health advisory for perfluorooctanoic acid (PFOA). (EPA822R16005). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.*

[27] U.S. EPA. (2016). Drinking water health advisory for perfluorooctane sulfonate (PFOS). (EPA822R16004). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf.*

[28] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[29] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[30] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

PFOS[31] and supporting documents for the Regulatory Determination 4 process[32] supports the conclusion that exposure to PFOA and PFOS can lead to adverse human health effects. As part of the final Regulatory Determination 4 process, the Agency concluded that exposure to PFOA and PFOS may have adverse health effects.[33]

Data from human and animal studies indicate that PFOA and PFOS are well absorbed via the oral route and are distributed throughout the body by noncovalent binding to serum albumin and other plasma proteins. PFOA and PFOS are slowly eliminated from the human body as evidenced by the half-life of 2.1–10.1 years for PFOA and 3.3–27 years for PFOS.[34] Because of their resistance to metabolic degradation, PFOA and PFOS are eliminated from mammals primarily unchanged.

Human epidemiology studies observed associations between PFOA exposure and high cholesterol, changes in liver enzymes, decreased immune response to vaccination, thyroid effects, pregnancy-induced hypertension and preeclampsia, low birth weight, and cancer (testicular and kidney).[35] Epidemiology studies have generally found a positive association between increasing serum PFOA and total cholesterol levels in PFOA-exposed workers and residents of high-exposure communities. In addition, associations between increasing serum PFOA concentrations and elevations in serum levels of alanine aminotransferase and gamma-glutamyl transpeptidase were consistently observed in occupational cohorts, high-exposure communities and the U.S. general population. This could indicate the potential for PFOA to affect liver function. A decreased response to vaccines was found to be associated with PFOA exposure in studies in adults in a highly exposed community and in studies of children in the general population. A study of a community with high exposure to PFOA observed an association between serum PFOA and risk of pregnancy-related hypertension or preeclampsia, conditions that are related to renal function during pregnancy. An association between increasing maternal PFOA or cord blood PFOA concentrations and decreasing birth weight was seen in several studies.[36]

Numerous epidemiology studies have examined occupational populations at large-scale PFOS production plants in the United States and the residential populations living near the PFOS production facilities to evaluate the association between increasing PFOS concentrations and various health outcomes. Data also suggest associations between higher PFOS levels and increases in total cholesterol and high-density lipoproteins, decreases in female fecundity and fertility, in addition to decreased offspring body weights and negative effects on other measures of postnatal growth. Evidence of an association between PFOS exposure and cancer is less conclusive.[37]

Perfluoroalkyl acids are transferred to the fetus during pregnancy and to breast milk through distribution due to their slow elimination from the human body through excretion.[38] Toxicity studies conducted in laboratory animal models demonstrate that the developing fetus is particularly sensitive to PFOA- and PFOS-induced toxicity. Some studies in laboratory animal models indicate that gestation and/or lactation periods are critical exposure windows that may lead to developmental health effects including decreased offspring survival, low birth weight, accelerated puberty and skeletal variations.[39 40 41]

Numerous animal toxicity studies for PFOA and PFOS are available and provide information about the potential for similar effects in humans. Animal studies and epidemiology studies indicate that PFOA and PFOS are well absorbed orally; absorption may also occur via the inhalation and dermal routes. Absorbed PFOA and/or PFOS are widely distributed in the body, with the highest concentrations typically found in the blood, liver and/or kidney. Across species, the highest extravascular concentrations of PFOA and PFOS are found in the liver, however, PFOA and/or PFOS have also been detected in many other tissues (*e.g.,* lung, kidney, spleen and bone). Though not readily, PFOS can cross the blood-brain barrier and has been detected at low levels in the brains of humans and rodents.[42 43 44]

PFOA and PFOS in blood bind to plasma albumin and other plasma proteins. Absorbed PFOA and PFOS are not metabolized and are eliminated by excretion primarily in urine. Active transport mechanisms mediate renal tubular reabsorption and secretion of PFOA and PFOS. Some excretion occurs through cord blood in pregnant women, and through lactation and menstrual blood loss. Although PFOA and PFOS are found in the bile of humans, they are reabsorbed from the bile and thus, fecal excretion is substantially lower than urinary excretion; levels in fecal matter represent both unabsorbed material and that discharged with bile.[45 46 47 48 49]

---

[31] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[32] U.S. EPA. (2021). Final regulatory determination 4 support document. (EPA815R21001). U.S. Environmental Protection Agency.

[33] Ibid.

[34] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[35] Ibid.

[36] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[37] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[38] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[39] Ibid.

[40] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[41] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[42] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[43] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[44] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[45] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[46] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[47] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[48] NJDWQI. (2017). Appendix A: Health-based maximum contaminant level support document perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute, Health Effects

Continued

For PFOA, oral studies of short-term (subchronic) and chronic duration are available in multiple species including monkeys, rats and mice. The animal studies report developmental effects, liver and kidney toxicity, immune effects and cancer (liver, testicular and pancreatic). The developmental effects observed in rodents include decreased survival, delayed eye opening, reduced ossification, skeletal defects, altered puberty (delayed vaginal opening in females and accelerated puberty in males) and altered mammary gland development.

For PFOS, numerous animal studies are available in multiple species including monkeys, rats and mice. Short-term and chronic exposure studies in animals demonstrate increases in liver weight, changes in cholesterol, hepatic steatosis, lower body weight and liver histopathological changes. One- and two- generation rodent toxicity studies also show decreased pup survival and body weights. Additionally, developmental neurotoxicity studies in rodents show increased motor activity, decreased habituation and increased escape latency in the water maze test (tests spatial learning and memory) following *in utero* and lactational exposure to PFOS. Gestational and lactational exposures were also associated with higher serum glucose levels and evidence of insulin resistance in adult offspring. Evidence suggests immunological effects in animal models.[50] [51]

The International Agency for Research on Cancer (IARC) concluded that PFOA is possibly carcinogenic to humans.[52] Study findings are mixed. While a mutagenic mode of action has not been established for PFOA or PFOS, studies indicate that PFOA (the more extensively studied of the two compounds) can induce deoxyribonucleic acid (DNA) damage.[53] In 2016, the EPA determined there is suggestive evidence that PFOA and PFOS may contribute to tumor development in humans.[54] [55] Epidemiology studies show an association between exposure to high levels of serum PFOA and testicular and kidney cancer in humans; two chronic bioassays in rats [56] [57] also support the finding that PFOA is tumorigenic (*i.e.,* capable of producing tumors).[58] Epidemiology studies establishing a correlation between PFOS exposure and the incidence of cancer are limited; however, a chronic toxicity and carcinogenicity study in rats provides some evidence of tumorigenicity.[59]

This information does not reflect recent scientific data that has been collected to support EPA's ongoing PFAS National Primary Drinking Water Regulation. The Agency's draft new analyses, released in November 2021 for independent scientific review by the EPA Science Advisory Board (SAB), indicate that negative health effects may occur at much lower levels of exposure to PFOA and PFOS than previously understood and that PFOA is likely carcinogenic to humans. The draft documents present EPA's initial analysis and findings with respect to this newly available updated information.[60] [61] Following SAB peer review, the final documents will be used to inform the development of Maximum Contaminant Level Goals and ultimately a National Primary Drinking Water Regulation for PFOA and PFOS. While this preliminary data was not used for this proposal, it appears to support designating PFOA and PFOS as hazardous substances.

In sum, studies have shown that exposure to PFOA and PFOS is associated with numerous and varied adverse effects to human health. This evidence plays a major role in the EPA's proposal to designate PFOA and PFOS as hazardous substances.

3. Environmental Prevalence

PFOA and PFOS are common contaminants in the environment because of their release into the environment since the 1940s and their resistance to degradation. PFOA and PFOS are found in many environmental media and in wildlife worldwide, including in remote polar regions. As an example, the polar bear, the top predator of arctic marine ecosystems, bioaccumulates high concentrations of PFAS (especially PFOS), which may be harmful to their health.[62]

Environmental sources can include direct industrial discharges of PFOA and PFOS to soil, air, and water. Precursors can also degrade to PFOA and/or PFOS (*e.g.,* perfluorooctanesulfonamide (PFOSA) can be transformed to PFOS in the environment). PFOA and PFOS precursors can be converted to PFOA and PFOS, respectively, by microbes in soil, sludge, and wastewater and through abiotic chemical reactions. PFOA and PFOS that are deposited, created by the degradation of their precursors in industrial and consumer

Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf.*

[49] NJDWQI. (2018). Appendix A: Health-based maximum contaminant level support document perfluorooctane sulfonate (PFOS). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf.*

[50] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[51] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[52] IARC. (2021). Agents classified by the IARC monographs, volumes 1–129. List of classifications. International Agency for Research on Cancer. *https://monographs.iarc.who.int/list-of-classifications.*

[53] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[54] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[55] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[56] NTP. (2020). NTP Technical report on the toxicology and carcinogenesis studies of perfluorooctanoic acid (CASRN 335–67–1) administered in feed to Sprague Dawley (Hsd:Sprague Dawley® SD®) rats. (NTP TR 598). Research Triangle Park, NC: National Toxicology Program. *https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr598_508.pdf?utm_source=direct&utm_medium=prod&utm_campaign=ntpgolinks&utm_term=tr598.*

[57] Butenhoff, J.L.; Kennedy, G.L.; Chang, S.; Olsen, G.W. (2012). Chronic dietary toxicity and carcinogenicity study with ammonium perfluorooctanoate in Sprague Dawley rats. Toxicology 298: 1–13.

[58] U.S. EPA. (2016). Health effects support document for perfluorooctanoic acid (PFOA). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.*

[59] U.S. EPA. (2016). Health effects support document for perfluorooctane sulfonate (PFOS). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_hesd_final_508.pdf.*

[60] U.S. EPA. (2021). Proposed approaches for deriving maximum contaminant level goals for PFOA in drinking water. (EPA822D21001). U.S. Environmental Protection Agency.

[61] U.S. EPA. (2021). Proposed approaches for deriving maximum contaminant level goals for PFOS in drinking water. (EPA822D21002). U.S. Environmental Protection Agency.

[62] Tartu, S.; Bourgeon, S.; Aars, J.; Andersen, M.; Lone, K.; Jenssen, B.M.; Polder, A.; Thiemann, G.W.; Torget, V.; Welker, J.M.; Routti, H. (2017). Diet and metabolic state are the main factors determining concentrations of perfluoroalkyl substances in female polar bears from Svalbard. Environ Pollut 229: 146–158. *https://www.ncbi.nlm.nih.gov/pubmed/28587979.* Tartu et al. (2017) found that the concentration of PFAS increased with the trophic level of female polar bears, which is consistent with other studies showing biomagnification of PFAS in Arctic marine ecosystems.

waste, in a landfill without environmental controls can discharge via leachates, groundwater pollution/migration and atmospheric releases.[63] [64] [65] The discharge of aqueous film-forming foam (AFFF) starting in the 1970s is also an important source for some locations. AFFF is a foam containing many PFAS, including PFOA and PFOS, which is effective at extinguishing petroleum fueled fires. PFAS, including PFOA and PFOS, were found in the soil and groundwater where AFFF was used to fight fires or for training and storage. Concrete where AFFF has been repeatedly discharged, such as for training activities, can absorb PFAS, including PFOA and PFOS, and then release PFAS to groundwater and soils during precipitation events.[66]

Industrial uses that have led to PFOA and PFOS in the soil and groundwater include, but are not limited to, chrome plating facilities where PFAS were used as a wetting agent/fume suppressant and industries where textiles and other materials are coated with PFAS. PFAS manufactured for use as a stain or water repellant may be released from these facilities into the air and wastewater.[67]

The principal worldwide manufacturers of PFOA and PFOS and related chemicals phased out their production in the early 2000's. PFOA and PFOS may still be produced domestically for certain uses and by international companies that import treated products to the United States.[68] Some uses of PFOS are ongoing, such as use as a component of a photoresist substance, including a photo acid generator or surfactant, or as a component of an anti-reflective coating, used in a photomicrolithography process to produce semiconductors or similar components of electronic or other miniaturized devices. Environmental contamination and resulting human exposure to PFOA and PFOS are declining, but are anticipated to continue for the foreseeable future due to their environmental persistence, formation from precursor compounds, continued production primarily by international manufacturers and their long history of production in the United States.[69]

Wastewater treatment plants (WWTPs) may receive wastewater that contains PFOA, PFOS or their precursors, from a variety of sources, including industries that manufacture or use these PFAS and their precursors. Some companies may operate onsite wastewater treatment facilities, but typically they are not designed to remove PFAS. PFOA and PFOS are the most widely detected PFAS in wastewater, and generally treatment units at conventional WWTPs do not remove PFAS efficiently.[70] Certain PFAS can be volatilized into the atmosphere from wastewater treatment plant operations, such as aeration chambers.[71] [72] Although effluent discharged to receiving water bodies may contain PFOA or PFOS, much of these substances may concentrate in the WWTP biosolids. Biosolids are also commonly applied to land as fertilizers or soil amendments but can also be sent to a landfill. The use of biosolids on farmland and home gardens can lead to the uptake of PFOA and PFOS in the food chain, as acknowledged by the U.S. Food and Drug Administration (FDA).[73] Biosolids from wastewater treatment plants and some industrial wastewater that is land applied are also potential sources of contamination.[74] [75]

PFAS have been found in outdoor air at locations in the United States, Europe, Japan, and over the Atlantic Ocean.[76] Concentrations are not generally correlated with rural or urban environments, but rather, around PFAS production industries and industries that use PFAS. Mean PFOA levels ranged from 1.54 to 15.2 picograms per cubic meter (pg/m^3) in air samples collected in the urban locations in Albany, New York, Fukuchiyama, Japan, and Morioka, Japan and in the rural locations in Kjeller, Norway, and Mace Head, Ireland. However, higher mean concentrations (101–552 pg/m^3) were measured at the urban locations in Oyamazaki, Japan, and Manchester, United Kingdom (UK), and semirural locations in Hazelrigg, UK. Maximum reported concentrations at Oyamazaki and Hazelrigg were 919 and 828 pg/m^3, respectively. Thus, there is no correlation between higher concentrations and urban versus rural locations; rather, high concentrations in certain locations may be attributable to a specific industrial plant.[77]

PFOA and PFOS are widely detected in surface water samples collected from various rivers, lakes, and streams in the United States.[78] Therefore, municipalities and other entities that use surface water sources for drinking water may face challenges treating and removing PFOA and PFAS from their finished drinking water. The most vulnerable drinking water systems are those in close proximity to sites contaminated with PFOA and PFOS.[79] Levels of these substances in surface water are declining since the major U.S.

[63] Lindstrom, A.B.; Strynar, M.J.; Libelo, E.L. (2011). Polyfluorinated compounds: past, present, and future. Environ Sci Technol 45: 7954–7961. *https://www.ncbi.nlm.nih.gov/pubmed/21866930.*

[64] Buck, R.C.; Franklin, J.; Berger, U.; Conder, J.M.; Cousins, I.T.; de Voogt, P.; Jensen, A.A.; Kannan, K.; Mabury, S.A.; van Leeuwen, S.P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integr Environ Assess Manag 7: 513–541. *https://www.ncbi.nlm.nih.gov/pubmed/21793199.*

[65] Oliaei, F.; Kriens, D.; Weber, R.; Watson, A. (2013). PFOS and PFC releases and associated pollution from a PFC production plant in Minnesota (USA). Environ Sci Pollut Res Int 20: 1977–1992. *https://www.ncbi.nlm.nih.gov/pubmed/23128989.*

[66] Baduel, C.; Paxman, C.J.; Mueller, J.F. (2015). Perfluoroalkyl substances in a firefighting training ground (FTG), distribution and potential future release. J. Hazard Mater 296: 46–53. *https://www.ncbi.nlm.nih.gov/pubmed/25966923.*

[67] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[68] Ibid.

[69] (ATSDR) Per- and Polyfluoroalkyl Substances (PFAS) and Your Health U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.*

[70] Rainey, M.; Beecher, N. (2018). PFAS in wastewater residuals. National Pretreatment & Pollution Prevention Workshop & Training. North East Biosolids & Residuals Association. *https://www.nacwa.org/docs/default-source/conferences-events/2018-pretreatment/18pret-m-rainey.pdf?sfvrsn=2.*

[71] Ma, R.; Shih, K. (2010). Perfluorochemicals in wastewater treatment plants and sediments in Hong Kong. Environ Pollut 158: 1354–1362. *https://www.ncbi.nlm.nih.gov/pubmed/20153098.*

[72] Ahrens, L.; Shoeib, M.; Harner, T.; Lee, S.C.; Guo, R.; Reiner, E.J. (2011). Wastewater treatment plant and landfills as sources of polyfluoroalkyl compounds to the atmosphere. Environ Sci Technol 45: 8098–8105. *https://www.ncbi.nlm.nih.gov/pubmed/21466185.*

[73] Genualdi, S.; deJager, L.; South, P.; Sheehan, J.; Begley, T. (2019). Investigation of PFAS concentrations in US food products. Center for Food Safety and Applied Nutrition, Food and Drug Administration. In SETAC Europe 29th annual meeting 26–30 May 2019 (pp. 357). Helsinki, Finland: Society of Environmental Toxicology and Chemistry.

[74] NJDWQI. (2018). Appendix A: Health-based maximum contaminant level support document perfluorooctane sulfonate (PFOS). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf.*

[75] NJDWQI. (2017). Appendix A: Health-based maximum contaminant level support document perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute, Health Effects Subcommittee. *https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf.*

[76] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[77] Ibid.

[78] Ibid.

[79] Ibid.

producers phased out these two substances.[80]

PFOA and PFOS have been detected in surface and subsurface soils. Levels of PFOA and PFOS generally increased with increasing depth at sampled locations, suggesting a downward movement of the contaminants and the potential to contaminate groundwater.[81] PFAS can be inadvertently released to soils when biosolids are applied as fertilizer to help maintain productive agricultural soils and stimulate plant growth.[82] PFOA and PFOS have been detected in both biosolids and biosolid-amended soils. PFAS can also reach soil due to atmospheric transport and wet/dry deposition.[83]

PFOA and PFOS have been detected in groundwater in monitoring wells, private drinking water wells, and public drinking water systems across the country. The EPA worked with the states and local communities to monitor for six PFAS, including PFOA and PFOS, under the third Unregulated Contaminant Monitoring Rule to understand the nationwide occurrence of these chemicals in the U.S. drinking water provided by public water systems (PWSs). Of the 4,920 PWSs with results for PFOA and PFOS, PFOA were detected above the minimum reporting level (minimum reporting level = 20 nanogram/liter (ng/L)) in 117 PWSs. Detections exceeded above the MRL for PFOS (MRL = 40 ng/L) at 95 PWSs.[84]

As previously stated, PFOA and PFOS are common contaminants in the environment because they and their precursors have been produced and released into the environment since the 1940s, and they are resistant to degradation. In addition to being found in groundwater, surface water, soil, sediment, and air, they have been found in wild and domestic animals such as fish, shellfish, alligators, deer and avian eggs; and in humans.[85] For example, PFOA has been found in snack foods, vegetables, meat, dairy products and fish, and PFOS has been found in eggs, milk, meat, fish and root vegetables.[86 87 88 89 90 91 92 93 94 95] In one study investigating the global distribution of PFAS, wildlife samples were collected on four continents including North America and Antarctica. Wildlife sampled included marine mammals, birds, and polar bears. Only a few samples contained PFOA in concentrations greater than the limit of quantification. However, over 30 different species had measurable levels of PFOS. The study reported PFOS concentrations in mink liver in the midwestern U.S. ranging from 970–3, 680 nanograms per gram (ng/g), river otter liver in northwestern U.S. from 34–990 ng/g, brown pelican liver in Mississippi from 290–620 ng/g, and lake whitefish eggs in Michigan waters from 150–380 ng/g.[96 97]

PFOS bioaccumulates in animals. A fish kinetic bioconcentration factor for PFOS has been estimated to range from 1,000 to 4,000.[98] The time to reach 50% clearance of PFOS in fish has been estimated to be around 100 days.[99] Bioaccumulation has been demonstrated for fish, birds, crustaceans, worms, plankton, and alligators, among others.[100 101 102]

PFOA bioaccumulates as well, but not to the same degree as PFOS.[103]

The prevalence of PFOA and PFOS in environmental media, wild animals, livestock, and plants not only affects the environment but can also lead to human exposure. PFOA and PFOS can also enter the drinking water supply from contamination in groundwater and surface water sources for drinking water. Contaminated drinking water or groundwater can also be used to irrigate or wash home-grown foods or farm-grown foods, thereby providing another means for human exposure. Wild animals are contaminated through environmental exposure, and some wild animals are caught or hunted and eaten by humans, thus, increasing human exposure. Contaminated water also results in the contamination of beef, pork, poultry, etc. Susceptible populations, such as women of reproductive age, pregnant and breastfeeding women, and young children who eat fish may have increased exposure to PFOA and PFOS due to bioaccumulation in fish.[104 105 106]

---

[80] Ibid.

[81] Ibid.

[82] Ibid.

[83] Ibid.

[84] U.S. EPA. (2017). The third Unregulated Contaminant Monitoring Rule (UCMR 3): Data summary, January 2017. (EPA815S17001). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf.*

[85] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.*

[86] U.S. EPA. (2016). Drinking water health advisory for perfluorooctanoic acid (PFOA). (EPA822R16005). U.S. Environmental Protection Agency, Office of Water. *https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.*

[87] U.S. EPA. (2016). Drinking water health advisory for perfluorooctane sulfonate (PFOS). (EPA822R16004). U.S. Environmental Protection Agency. *https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf.*

[88] Holmstrom, K.E.; Jarnberg, U.; Bignert, A. (2005). Temporal trends of PFOS and PFOA in guillemot eggs from the Baltic Sea, 1968–2003. Environ Sci Technol 39: 80–84. *https://www.ncbi.nlm.nih.gov/pubmed/15667078.*

[89] Wang, Y.; Yeung, L.W.Y.; Yamashita, N.; Taniyasu, S.; So, M.K.; Murphy, M.B.; Lam, P.K.S. (2008). Perfluorooctane sulfonate (PFOS) and related fluorochemicals in chicken egg in China. Chinese Science Bulletin 53: 501–507.

[90] Gewurtz, S.B.; Martin, P.A.; Letcher, R.J.; Burgess, N.M.; Champoux, L.; Elliott, J.E.; Weseloh, D.V.C. (2016). Spatio-temporal trends and monitoring design of perfluoroalkyl acids in the eggs of gull (Larid) species from across Canada and parts of the United States. Sci Total Environ 565: 440–450. *https://www.ncbi.nlm.nih.gov/pubmed/27183458.*

[91] Morganti, M.; Polesello, S.; Pascariello, S.; Ferrario, C.; Rubolini, D.; Valsecchi, S.; Parolini, M. (2021). Exposure assessment of PFAS-contaminated sites using avian eggs as a biomonitoring tool: A frame of reference and a case study in the Po River valley (Northern Italy). Integr Environ Assess Manag 17: 733–745. *https://www.ncbi.nlm.nih.gov/pubmed/33764673.*

[92] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Fish and wildlife. PFAS in deer. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86512_88981_88982—,00.html.*

[93] Wisconsin DNR. (2020). DNR And DHS issue do not eat advisory for deer liver in five-mile area surrounding JCI/TYCO site in Marinette. Wisconsin Department of Natural Resources. *https://dnr.wisconsin.gov/newsroom/release/37921.*

[94] Falk, S.; Brunn, H.; Schroter-Kermani, C.; Failing, K.; Georgii, S.; Tarricone, K.; Stahl, T. (2012). Temporal and spatial trends of perfluoroalkyl substances in liver of roe deer (Capreolus capreolus). Environ Pollut 171: 1–8. *https://www.ncbi.nlm.nih.gov/pubmed/22868342.*

[95] Bangma, J.T.; Reiner, J.L.; Jones, M.; Lowers, R.H.; Nilsen, F.; Rainwater, T.R.; Somerville, S.; Guillette, L.J.; Bowden, J.A. (2017). Variation in perfluoroalkyl acids in the American alligator (Alligator mississippiensis) at Merritt Island National Wildlife Refuge. Chemosphere 166: 72–79. *https://www.ncbi.nlm.nih.gov/pubmed/27689886.*

[96] Giesy, J.P.; Kannan, K. (2001). Global distribution of perfluorooctane sulfonate in wildlife. Environ Sci Technol 35: 1339–1342. *https://www.ncbi.nlm.nih.gov/pubmed/11348064.*

[97] EFSA. (2008). Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts Scientific Opinion of the Panel on Contaminants in the Food chain. EFSA Journal 6.

[98] Ibid.

[99] Ibid.

[100] Bangma, J.T.; Reiner, J.L.; Jones, M.; Lowers, R.H.; Nilsen, F.; Rainwater, T.R.; Somerville, S.; Guillette, L.J.; Bowden, J.A. (2017). Variation in perfluoroalkyl acids in the American alligator (Alligator mississippiensis) at Merritt Island National Wildlife Refuge. Chemosphere 166: 72–79. *https://www.ncbi.nlm.nih.gov/pubmed/27689886.*

[101] Ng, C.A.; Hungerbuhler, K. (2014). Bioaccumulation of perfluorinated alkyl acids: observations and models. Environ Sci Technol 48: 4637–4648. *https://www.ncbi.nlm.nih.gov/pubmed/24762048.*

[102] Burkhard, L.P. (2021). Evaluation of published bioconcentration factor (BCF) and bioaccumulation factor (BAF) data for per- and polyfluoroalkyl substances across aquatic species. Environ Toxicol Chem 40: 1530–1543. *https://www.ncbi.nlm.nih.gov/pubmed/33605484.*

[103] *https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/etc.5010.*

[104] U.S. EPA. (2019). Fish and shellfish program newsletter. (EPA823N19002). U.S. Environmental

Human exposure is confirmed by measurements of PFOA and PFOS that were detected in human serum as part of the continuous National Health and Nutrition Examination Survey (NHANES), a program of the CDC. PFOA and PFOS were measured in the serum of a representative sample of the U.S. population ages 12 years and older in each two-year cycle of NHANES since 1999–2000, with the exception of 2001–2002. PFOA and PFOS have been detected in 99% of those surveyed in each NHANES cycle. However, the mean concentrations of PFOA and PFOS in the serum have been steadily decreasing since 1999–2000.[107] [108]

Taken together, this information illustrates the prevalence of PFOA and PFOS in water, soil, air, plants, and animals worldwide due to its transportability and persistence. This widespread distribution of these PFAS significantly contributes to the EPA's proposed finding that PFOA and PFOS, when released into the environment may present substantial danger to the public health or welfare or the environment.

EPA's proposal to designate PFOA and PFOS, and their salts and structural isomers, as hazardous substances under CERCLA section 102(a) is based on significant evidence, summarized above, that indicates, when released into the environment, these substances may present substantial danger to the public health, welfare or the environment. Collectively, this information demonstrates that PFOA and PFOS should be designated as hazardous substances under CERCLA.

VI. Effect of Designation

The designation of PFOA and PFOS would have three direct effects—triggering reporting obligations when there is a release of PFOA or PFOS above the reportable quantity, obligations on the U.S. Government when it transfers certain properties, and an obligation on DOT to list and regulate CERCLA designated hazardous substances as hazardous materials.

A. Default Reportable Quantity

Section 102(b) of CERCLA provides that, until superseded by regulation, the reportable quantity for any hazardous substance is one pound. This proposed rule does not include an RQ adjustment for PFOA or PFOS. EPA is setting the RQ by operation of law at the statutory default of one pound pursuant to Section 102(b) of CERCLA. If the Agency chooses to propose adjusting the RQ in the future, it would do so through notice-and-comment rulemaking.

B. Direct Effects of a Hazardous Substance Designation

1. Reporting and Notification Requirements for CERCLA Hazardous Substances

Section 103 of CERCLA requires any person in charge of a vessel or facility to immediately notify the NRC when there is a release of a hazardous substance, as defined under CERCLA section 101(14), in an amount equal to or greater than the RQ for that substance. The reporting requirements are further codified in 40 CFR 302.6. If this action is finalized, any person in charge of a vessel or facility as soon as he or she has knowledge of a release from such vessel or facility of one pound or more of PFOA or PFOS in a 24-hour period is required to immediately notify the NRC in accordance with 40 CFR part 302. EPA solicits comment on the number of small entities affected by and the estimated cost impacts on small entities from these reporting requirements.

In addition to these CERCLA reporting requirements, EPCRA section 304 also requires owners or operators of facilities to immediately notify their SERC (or TERC) and LEPC (or TEPC) when there is a release of a CERCLA hazardous substance in an amount equal to or greater than the RQ for that substance within a 24-hour period. EPCRA section 304 requires these facilities to submit a follow-up written report to the SERC (or TERC) and LEPC (or TEPC) within 30 days of the release. (Note: Some states provide less than 30 days to submit the follow-up written report. Facilities are encouraged to contact the appropriate state or tribal agency for additional reporting requirements.) See 40 CFR part 355, subpart C, for information on the contents for the initial telephone notification and the follow-up written report.

EPCRA and CERCLA are separate, but interrelated, environmental laws that work together to provide emergency release notifications to Federal, state, Tribal, and local officials. Notice given to the NRC under CERCLA serves to inform the Federal government of a release so that Federal personnel can evaluate the need for a response in accordance with the National Oil and Hazardous Substances Contingency Plan, the Federal government's framework for responding to both oil and hazardous substance releases. The NRC maintains all reports of hazardous substance and oil releases made to the Federal government.

Relatedly, release notifications under EPCRA given to the SERC (or TERC) and to the LEPC (or TEPC) are crucial so that these state, Tribal, and local authorities have information to help protect the community.

2. Requirements Upon Transfer of Government Property

Under CERCLA section 120(h), when Federal agencies sell or transfer federally-owned, real property, they must provide notice of when any hazardous substances ''was stored for one year or more, known to have been released, or disposed of'' and covenants concerning the remediation of such hazardous substances in certain circumstances.

3. Requirement of DOT To List and Regulate CERCLA Hazardous Substances

Section 306(a) of CERCLA requires substances designated as hazardous under CERCLA be listed and regulated as hazardous materials by DOT under the Hazardous Materials Transportation Act (HMTA). DOT typically does not undertake a public notice and comment period when adding a CERCLA-designated hazardous substance to the list of regulated hazardous materials under HMTA.

VII. Regulatory and Advisory Status at EPA, Other Federal, State and International Agencies

Designating PFOA and PFOS as hazardous substances would be one additional piece of an extensive, widespread response to address the dangers these chemicals pose. Regulatory requirements, enforcement actions, and other activities of many Federal, state, and international entities together indicate the widespread and serious concern with PFOA and PFOS.

Protection Agency. *https://www.epa.gov/sites/production/files/2019-04/documents/fish-news-mar2019.pdf.*

[105] FDA. (2021). Testing food for PFAS and assessing dietary exposure. U.S. Food and Drug Administration. *https://www.fda.gov/food/chemical-contaminants-food/testing-food-pfas-and-assessing-dietary-exposure.*

[106] Christensen, K.Y.; Raymond, M.; Blackowicz, M.; Liu, Y.; Thompson, B.A.; Anderson, H.A.; Turyk, M. (2017). Perfluoroalkyl substances and fish consumption. Environ Res 154: 145–151. *https://www.ncbi.nlm.nih.gov/pubmed/28073048.*

[107] CDC. (2021). National Health and Nutrition Examination Survey: NHANES questionnaires, datasets, and related documentation. Centers for Disease Control and Prevention. *https://wwwn.cdc.gov/nchs/nhanes/Default.aspx.*

[108] U.S. EPA. (2019). EPA's per- and polyfluoroalkyl substances (PFAS) action plan. (EPA823R18004). U.S. Environmental Protection Agency. *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100W32I.txt.*

A. EPA Actions

The EPA has taken several actions in the past to address risks from PFOA and PFOS. In 2006, the EPA launched the 2010/2015 PFOA Stewardship Program, under which eight major chemical manufacturers and processors agreed to phase out the use of PFOA and PFOA-related chemicals in their products and emissions from their facilities. All companies met the PFOA Stewardship Program goals by 2015.

The TSCA program has taken a range of regulatory actions to address PFAS in manufacturing and consumer products. Since 2002, EPA has finalized a number of TSCA Section 5(a) Significant New Use Rules (SNURs) covering hundreds of existing PFAS no longer in use. These regulatory actions require notice to EPA, as well as Agency review and regulation, as necessary, before manufacture (including import) or processing for significant new uses of these chemicals can begin or resume. The SNURs also apply to imported articles containing certain PFAS, including consumer products such as carpets, furniture, electronics, and household appliances. EPA also has issued SNURs for dozens of PFAS that have undergone EPA's new chemicals review prior to commercialization; these actions ensure that any new uses which may present risk concerns but were not part of the EPA new chemicals review, do not commence unless EPA is notified, conducts a risk review, and regulates as appropriate under TSCA section 5.

In 2009, EPA published provisional drinking water health advisories of 400 ppt for PFOA and 200 ppt for PFOS based on health effects information available at that time. The provisional health advisories were developed for application to short-term (weeks to months) risk assessment exposure scenarios. The provisional health advisories were intended as guidelines for public water systems while allowing time for EPA to develop final lifetime health advisories for PFOA and PFOS. EPA published final lifetime drinking water health advisories for PFOA and PFOS (70 ppt individually, and in combination) in 2016.

New health information has become available since 2016, and in June 2022, EPA replaced the 2016 advisories with interim updated lifetime health advisories for PFOA and PFOS based on human epidemiology studies in populations exposed to these chemicals. Based on the new data and EPA's draft analyses, the levels at which negative health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS. The interim updated health advisory levels are 0.004 ppt for PFOA and 0.02 ppt for PFOS, which are below the levels at which analytical methods can measure these PFAS in drinking water. The EPA Science Advisory Board is reviewing EPA's analyses, and therefore, the interim health advisories are subject to change. However, EPA does not anticipate changes that will result in health advisory levels that are greater than the minimum reporting levels. The interim health advisories are intended to provide information to states and public water systems until the PFAS National Primary Drinking Water Regulation takes effect. Health advisories provide drinking water system operators, and state, Tribal, and local officials who have the primary responsibility for overseeing these systems, with information on the health risks of these chemicals, so they can take the appropriate actions to protect their residents.

In 2019, EPA issued the *Interim Recommendations to Address Groundwater Contaminated with PFOA and PFOS* to facilitate cleaning up contaminated groundwater that is a current or potential source of drinking water. The recommendations provide a starting point for making site-specific cleanup decisions. The guidance recommends: [109]

- Use the following tapwater screening levels for PFOA and PFOS to determine if PFOA and/or PFOS is present at a site and may warrant further attention.
  - If both are detected in tapwater—PFOS regional screening level (RSL) = 6 parts per trillion (ppt) and PFOS regional removal management levels (RMLs) = 4 ppt.
  - If they are the only contaminant detected in tapwater—PFOA RSL = 60 ppt and PFOS RSL = 40 ppt.
  - Screening levels are risk-based values that are used to determine if levels of contamination may warrant further investigation at a site.
- Using EPA's 2016 PFOA and PFOS LHA level of 70 ppt as the preliminary remediation goal (PRG) for contaminated groundwater that is a current or potential source of drinking water, where no state or tribal maximum contaminant level (MCL) or other applicable or relevant and appropriate requirements are available or sufficiently protective.
  - PRGs are generally initial targets for cleanup that may be adjusted on a site-specific basis as more information becomes available.

In 2020, the EPA issued a final rule strengthening the regulation of PFAS (*i.e.,* PFOA and its salts, long-chain perfluoroalkyl carboxylate chemical substances) by requiring notice and EPA review before the use of long-chain PFAS that have been phased out in the United States could begin again. Additionally, products containing certain long-chain PFAS as a surface coating and carpet containing perfluoroalkyl sulfonate chemical substances can no longer be imported into the United States without EPA review. This action means that articles like textiles, carpet, furniture, electronics, and household appliances that could contain certain PFAS cannot be imported into the United States unless EPA reviews and approves the use or puts in place the necessary restrictions to address any unreasonable risks.

In 2020, the EPA also added 172 PFAS (including PFOA and PFOS) to the TRI, and 3 additional compounds were added in 2021. Additional PFAS will continue to be added to TRI, consistent with the National Defense Authorization Act for Fiscal Year 2020.

In October 2021, the EPA released the PFAS Strategic Roadmap that presents EPA's whole-of-agency approach to addressing PFAS and sets timelines by which the Agency plans to take concrete actions.[110] Several actions described in the roadmap, including this proposed rule, address PFOA and PFOS. Other ongoing EPA actions on PFOA and PFOS include:

- Finalizing a proposed rule that would impose certain reporting and recordkeeping requirements under TSCA for PFAS, including PFOA and PFOS, manufactured at any time since January 1, 2011 (86 FR 33926).
- Finalizing the proposed Unregulated Contaminant Monitoring Rule 5 (UCMR5). As proposed, UCMR5 would collect data on 29 PFAS, including PFOA and PFOS, in public water systems (86 FR 13846).
- Establishing a national primary drinking water regulation for PFOA and PFOS under the Safe Drinking Water Act.
- Publishing recommended aquatic life water quality criteria for PFOA and

[109] U.S. EPA. (2019). USEPA draft interim recommendations to address groundwater contaminated with perfluorooctanoic acid and perfluorooctane sulfonate. (EPA–HQ–OLEM–2019–0229–0002). U.S. Environmental Protection Agency. *https://downloads.regulations.gov/EPA-HQ-OLEM-2019-0229-0002/content.pdf.*

[110] U.S. EPA. (2021). PFAS strategic roadmap: EPA's commitments to action 2021–2024. U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.*

PFOS (draft criteria were released for public comment in May 2022) and developing human health water quality criteria for PFOA and PFOS.

• Finalizing a risk assessment for PFOA and PFOS in biosolids, which will serve as the basis for determining whether regulation of PFOA and PFOS in biosolids is appropriate.

Further, based on public health and environmental protection concerns, and in response to a petition from the Governor of New Mexico, which requested EPA to take regulatory action on PFAS under RCRA, EPA announced on October 26, 2021, the initiation of two rulemakings. First, EPA will initiate the rulemaking process to propose adding four PFAS as RCRA hazardous constituents under 40 CFR part 261 Appendix VIII, by evaluating the existing data for these chemicals and establishing a record to support such a proposed rule. The four PFAS EPA will evaluate are: PFOA, PFOS, perfluorobutane sulfonic acid (PFBS) and GenX chemicals (hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt). Second, EPA will initiate a rulemaking to clarify in the Agency's regulations that the RCRA Corrective Action Program has the authority to require investigation and cleanup for wastes that meet the statutory definition of hazardous waste, as defined under RCRA section 1004(5). This modification would clarify that emerging contaminants such as PFAS can be addressed through RCRA corrective action.

Recent scientific data and the Agency's new analyses indicate that negative health effects may occur at much lower levels of exposure to PFOA and PFOS than previously understood and that PFOA is likely carcinogenic to humans. The Agency's new analyses were released in November 2021 [111] [112] for independent scientific review by the EPA Science Advisory Board. The draft documents present EPA's initial analysis and findings with respect to this new information. EPA's 2021 draft non-cancer reference doses based on human epidemiology studies for various effects (*e.g.,* developmental/growth, cardiovascular health outcomes, immune health) range from ~10^{-7} to 10^{-9} milligram per kilogram per day (mg/kg/day). These draft reference doses are two to four orders of magnitude lower than EPA's 2016 reference doses for PFOA and PFOS of 2×10^{-5} mg/kg/day. Following peer review, this information will be used to inform updated EPA drinking water health advisories and the development of Maximum Contaminant Level Goals and a National Primary Drinking Water Regulation for PFOA and PFOS.

The EPA routinely updates RSLs and RMLs two times per year. EPA's next regularly scheduled update to the RSL and RML tables will be in November 2022. Since the science of PFAS toxicity is evolving we expect to update the numbers as appropriate during future updates.

B. Actions by Other Federal Agencies

• *ATSDR:* The Agency for Toxic Substances and Disease Registry (ATSDR), in response to a congressional mandate under CERCLA, develops comparison values to help identify chemicals that may be of concern to the public's health at hazardous waste sites. The ATSDR's guideline values are minimal risk levels (MRLs). An MRL is an estimate of the amount of a chemical a person can eat, drink, or breathe each day over a specified duration without a detectable risk to health. MRLs are developed for health effects other than cancer. If someone is exposed to an amount above the MRLs, it does not mean that health problems will happen. MRLs are a screening tool that help identify exposures that could be potentially hazardous to human health. Exposure above the MRLs does not mean that health problems will occur. Instead, it may act as a signal to health assessors to look more closely at a particular site where exposures may be identified.

The ATSDR works closely with EPA at both a national and regional level to determine areas and populations potentially at risk for health effects from exposure to PFAS.[113] The ATSDR has final intermediate duration (15–364 days) MRLs (2021) for PFOA and PFOS which are 3×10^{-6} mg/kg/day and 2×10^{-6} mg/kg/day, respectively.[114] ATSDR also has a PFAS strategy, exposure assessments, and a multi-site study—PFAS Cooperative Agreement.

• *DoD:* The Department of Defense (DoD) included PFOA and PFOS on its list of emerging chemicals of concern.[115] The DoD defines emerging chemicals as chemicals or materials that the department currently uses or plans to use that present a potentially unacceptable human health or environmental risk; have a reasonably possible pathway to enter the environment; and either do not have regulatory standards based on peer-reviewed science, or their regulatory standards are evolving due to new science, detection capabilities or exposure pathways.[116]

In 2017, the DoD updated their military specification for AFFF to include no more than 800 parts per billion, the quantitation limit by DoD Quality Systems Manual 5.1, of PFOA and PFOS in the concentrate.[117] The DoD is working to remove AFFF containing PFOA and PFOS from the supply chain.[118] ''In January 2016, the Office of the Assistant Secretary of Defense for Energy, Installations and Environment issued a policy requiring the DoD components to: (1) issue Military Service-specific risk management procedures to prevent uncontrolled land-based releases of AFFF during maintenance, testing and training activities, and (2) remove and properly dispose of AFFF containing PFOS from the local stored supplies for non-shipboard use to prevent future environmental response action costs, where practical''.[119] Under this policy,

[111] U.S. EPA (U.S. Environmental Protection Agency). 2021a. External Peer Review Draft: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335–67–1) in Drinking Water. EPA–822–D–21–001. EPA, Office of Water, Washington, DC. Accessed April 2022. *https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.*

[112] U.S. EPA (U.S. Environmental Protection Agency). 2021b. External Peer Review Draft: Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) CASRN 1763–23–1 in Drinking Water. EPA–822–D–21–002. EPA, Office of Water, Washington, DC. Accessed April 2022. *https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.*

[113] ATSDR. (2018). Minimal risk levels (MRLs). Atlanta, GA: Agency for Toxic Substances and Disease Registry. *https://www.atsdr.cdc.gov/minimalrisklevels/.*

[114] ATSDR. (2021). Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. *https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237.*

[115] DoD. (2019). DoD instruction 4715.18: Emerging chemicals (ECs) of environmental concern. U.S. Department of Defense. *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/471518p.pdf?ver=2017-12-13-110558-727.*

[116] Ibid.

[117] U.S. Navy. (2017). Performance specification fire extinguishing agent, aqueous film-forming foam (AFFF) liquid concentrate, for fresh and sea water. (MIL–PRF–24385F(SH) w/Amendment 2). U.S. Navy, Naval Sea Systems Command (Ship Systems). *https://quicksearch.dla.mil/Transient/E3EA5BB276A741A292E87C18DE644702.pdf https://quicksearch.dla.mil/Transient/C26F946AAE39463BBFCB321B047611E4.pdf.*

[118] *WH.gov.* (2021). Fact sheet: President Biden signs executive order catalyzing America's clean energy economy through federal sustainability. Washington, DC: The White House. *https://www.whitehouse.gov/briefing-room/statements-releases/2021/12/08/fact-sheet-president-biden-signs-executive-order-catalyzing-americas-clean-energy-economy-through-federal-sustainability/.*

[119] DoD. (2017). Aqueous film forming foam: Report to Congress. U.S. Department of Defense, Continued

for example, the Air Force funded the removal of AFFF from all fire trucks and crash response vehicles and replaced it with PFOS-free AFFF, which contains only trace quantities of PFOA. All Air Force bases except Thule Air Force Base, Greenland, have received replacement AFFF, and 97 percent of the bases have completed the transition. In addition, the Navy is updating the military specification requirements for AFFF and DoD continues its research efforts to find a PFAS-free alternative to AFFF.[120] DoD has also set up a taskforce to address PFAS on and near military bases from DoD activities.

DoD is investing over $49 million through fiscal year 2025 in research, development, testing, and evaluation in collaboration with academia and industry to identify alternative firefighting material and practices. In the meantime, DoD only uses AFFF to respond to emergency events and no longer uses it for uncontained land-based testing and training.[121]

In addition, DoD has initiated other actions to test for, investigate, and mitigate elevated levels of PFOA and PFOS at or near installations across the military departments. Following the release of EPA's LHAs for PFOA and PFOS in May 2016, each of the military departments issued guidance directing installations to test for PFOA and PFOS in their drinking water and take steps to address drinking water that contained amounts of PFOA and PFOS above EPA's health advisory level. The military departments also directed their installations to identify locations with a known or suspected prior release of PFOA and PFOS and to address any releases that pose a risk to human health.[122] As of December 31, 2021, the DoD was performing the PA/SI for PFAS at 700 DoD installations and National Guard Facilities.

• *DOE:* On September 16, 2021, the Department of Energy (DOE) issued a memo that focused on four main points; discontinue use of AFFF except in emergencies, suspend disposal of AFFF pending further guidance, establish reporting requirements for any release or spill of PFAS and establish a DOE PFAS Coordinating Committee. DOE has completed an assessment of its PFAS usage and inventory across the department and is in the process of developing a department wide report of the results of that assessment. At the request of Council on Environmental Quality, DOE, as well as other agencies and departments, is developing a PFAS Roadmap similar to EPA's that will guide future PFAS related actions for 2022–2025.FAA: On January 17, 2019, the Federal Aviation Administration (FAA) released guidance in the form of a CertAlert to all certificated Part 139 Aircraft Rescue and Firefighting departments regarding safer methods for the required bi-annual testing of AFFF for firefighting. In the guidance, the FAA suggests alternative AFFF testing systems that minimize environmental impact while still satisfying the regulatory requirement for safety testing. The recommendations include addressing environmental concerns such as establishing safe and environmentally effective handling and disposal procedures.[123]

On October 4, 2021, the FAA published a CertAlert which informs Part 139 airport operators about changes to the military specification (MIL–PRF–24385F(SH)) for firefighting foam referenced in Chapter 6 of AC No.: 150/5210–6D. While the performance standard remains the same, the military specification no longer requires the use of fluorinated chemicals. One acceptable means of satisfying 14 CFR part 139 requirements is to continue to use the existing approved foam which does contain fluorinated chemicals. However, FAA encourages certificate holders that have identified a different foam that meets the performance standard to seek approval for such foam from the FAA.[124]

• *FDA:* In 2011, FDA reached voluntary agreements with manufacturers and suppliers of long chain PFAS subject to Food Contact Notification to no longer sell those substances for use in food contact applications. In 2016, the FDA revoked the regulations authorizing the remaining uses of these long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016, and 81 FR 83672, November 22, 2016). As of November 2016, long-chain PFAS are no longer used in food contact applications sold in the United States.[125]

In addition to EPA, a number of agencies including ATSDR, DoD, DOI, DOT, FDA, and USDA Have or are developing PFAS plans outlining how their agencies will address PFAS contamination.

C. State Actions

As concerns have arisen regarding PFOA and PFOS many states have taken regulatory action.

In addition to some of the states discussed in more detail below, Alabama, Arizona, Idaho, Kentucky, Nebraska, and West Virginia have opted to use EPA's 2016 LHAs of 70 ppt for PFOA and PFOS.[126] [127] [128] [129]

• *Alaska:* The Alaska Department of Environmental Conservation (ADEC) promulgated groundwater cleanup levels of 400 ppt and soil cleanup levels of 1.3 to 2.2 milligram per kilogram (mg/kg) (range depending on precipitation zone) for PFOA and PFOS, respectively, in Oil and Other Hazardous Substances Pollution Control Regulations as amended through June 2021.[130] Health-based action levels for drinking water of 70 ppt for PFOA and PFOS, individually or combined, were established by ADEC in 2018 (updated in 2019) based on EPA's 2016 LHAs.[131]

• *California:* In August 2019, the California Office of Environmental Health Hazard Assessment developed PFOA and PFOS toxicity values

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics. *https://www.denix.osd.mil/derp/home/documents/aqueous-film-forming-foam-report-to-congress/Aqueous%20Film%20Forming%20Foam%20(AFFF)%20Report%20to%20Congress_DENIX.PDF.*

[120] DoD. (2020). Per- and polyfluoroalkyl substances (PFAS) Task Force progress report. U.S. Department of Defense. *https://media.defense.gov/2020/Mar/13/2002264440/-1/-1/1/PFAS_Task_Force_Progress_Report_March_2020.pdf.*

[121] Ibid.

[122] Ibid.

[123] FAA. (2019). National part 139 CertAlert: Aqueous film forming foam (AFFF) testing at certificated part 139 airports. (No. 19–01). Federal Aviation Administration. *https://www.faa.gov/airports/airport_safety/certalerts/media/part-139-cert-alert-19-01-AFFF.pdf.*

[124] FAA. (2021). National part 139 CertAlert: Part 139 extinguishing agent requirements. (No. 21–05). Federal Aviation Administration. *https://www.faa.gov/airports/airport_safety/certalerts/media/part-139-cert-alert-21-05-Extinguishing-Agent-Requirements.pdf.*

[125] *https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications.*

[126] Pontius, F. (2019). Regulation of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water: A comprehensive review. Water 11: 2003.

[127] Idaho DEQ. (2021). PFAS and Idaho drinking water. Idaho Department of Environmental Quality. *https://www.deq.idaho.gov/water-quality/drinking-water/pfas-and-idaho-drinking-water/.*

[128] Kentucky EEC. (2019). Evaluation of Kentucky community drinking water for per- & poly-fluoroalkyl substances. Kentucky Energy and Environment Cabinet, Department for Environmental Protection. *https://eec.ky.gov/Documents%20for%20URLs/PFAS%20Drinking%20Water%20Report%20Final.pdf.*

[129] AWWA. (2020). Per- and polyfluoroalkyl substances (PFAS): summary of state policies to protect drinking water. American Water Works Association. *https://www.awwa.org/LinkClick.aspx?fileticket=nCRhtmGcA3k%3D&portalid=0.*

[130] Alaska DEC. (2021). Oil and other hazardous substances pollution control. (Alaska Admin Code 18 AAC 75). Alaska Department of Environmental Conservation. *https://dec.alaska.gov/commish/regulations/.*

[131] Alaska DEC. (2019). Technical memorandum: Action levels for PFAS in water and guidance on sampling groundwater and drinking water. Alaska Department of Environmental Conservation. *https://dec.alaska.gov/media/15773/pfas-drinking-water-action-levels-technical-memorandum-10-2-19.pdf.*

(acceptable daily doses) of 4.5×10^{-7} mg/kg-day and 1.8×10^{-6} mg/kg-day, respectively, and reference levels based on cancer effects of 0.1 ppt and 0.4 ppt, respectively. They noted that the levels are lower than the levels of PFOA and PFOS that can be reliably detected in drinking water using currently available technologies. Thus, they recommended that the State Water Resources Control Board set notification limits at the lowest levels at which PFOA and PFOS can be reliably detected in drinking water using available and appropriate technologies.[132] The California State Water Resources Control Board issued new drinking water notification limits for local water agencies to follow for finding and reporting PFOA and PFOS of 5.1 ppt for PFOA and 6.5 ppt for PFOS. As part of these guidelines, California also established a response level of 10 ppt for PFOA and 40 ppt for PFOS.[133] [134] If this level is exceeded in drinking water provided to consumers, California recommends that the water agency remove the water source from service.[135]

In July 2021, the California Office of Environmental Health Hazard Assessment released draft Public Health Goals (PHGs) for PFOA of 0.007 ppt based on human kidney cancer data and PFOS of 1 ppt based on liver and pancreatic tumor animal data. PHGs are not regulatory requirements and are based solely on protection of public health without regard to cost impacts or other factors.[136]

California is also conducting sampling efforts targeting airports, chrome plating facilities, landfills, WWTPs and nearby water supply wells.[137]

• *Colorado:* To address known contamination in El Paso County, the Colorado Water Quality Control Commission (WQCC) adopted a site-specific groundwater quality standard of 70 ppt for PFOA and PFOS combined in 2018 based on the EPA 2016 LHAs.[138] [139] By 2019, the Colorado Department of Public Health and Environment adopted a PFAS Action Plan outlining methods by which the state planned to protect residents from PFAS. As part of this initiative, a survey was conducted regarding the use of firefighting foams that resulted in rules with respect to the registration and use of PFAS-containing foams.[140] The Colorado WQCC approved a policy interpreting the existing narrative standards for PFAS in 2020. This policy outlines the use of translation levels of 70 ppt for PFOA, PFOS, PFOA and PFOS parent constituents, and perfluorononanoic acid (PFNA), individually or combined, based on the EPA's 2016 LHAs.[141]

• Connecticut has issued a drinking water action level of 70 ppt for PFOA, PFOS, PFNA, perfluorohexanesulfonic acid (PFHxS) and perfluoroheptanoic acid (PFHpA) individually or combined. The action level is based on risk and similar health effects of the five PFAS. An interagency task force was formed that has recommended actions including take-back and safe disposal of AFFF containing PFAS from state and municipal fire departments.[142]

• *Delaware:* Based on Delaware's Department of Natural Resources and Environmental Control Hazardous Substance Cleaning Act Screening Level Table Guidance (last updated in November 2021), a screening/reporting level for PFOA and PFOS, individually or combined, of 70 ppt in groundwater is based on EPA's 2016 LHAs; and a reporting/screening level for PFOA and PFOS in the soil (of 0.13 mg/kg based on screening document and 1.3 mg/kg based on the reporting level table) is based on EPA's Regional Screening Level Calculator.[143] [144]

• Florida issued guidance identifying provisional groundwater target cleanup levels of 70 ppt for PFOA and PFOS combined, provisional soil cleanup target levels of 1.3 mg/kg for PFOA and PFOS, and surface water screening levels of 500 ppt for PFOA and 10 ppt for PFOS; these values were last updated in 2020.[145]

• *Hawaii:* In 2020, Hawaii published a memorandum identifying interim soil and water and soil environmental action levels (EALs) for PFAS. For groundwater that is a current potential source of drinking water, groundwater EALs are 40 ppt for PFOA and PFOS. Soil EALs are 0.0012 mg/kg for PFOA and 0.0075 mg/kg for PFOS.[146]

• *Illinois:* By July 2021, Illinois EPA issued statewide health advisories for six PFAS: PFOA, PFOS, PFNA, perfluorohexanoic acid (PFHxA), PFHxS and PFBS. A health advisory is a regulatory action that provides guidance to local officials and community water supply operators in protecting the health of their customers. Illinois EPA is authorized to issue a health advisory when there is a confirmed detection in a community water supply well of a chemical substance for which no

[132] OEHHA. (2019). Notification level recommendations: Perfluorooctanoic acid and perfluorooctane sulfonate in drinking water. California Office of Environmental Health Hazard Assessment. *https://oehha.ca.gov/media/downloads/water/chemicals/nl/final-pfoa-pfosnl082119.pdf.*

[133] California Water Boards. (2020). Notification level issuance: Contaminant(s): perfluorooctanoic acid (PFOA). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfoa_nl_issuance_jan2020.pdf.*

[134] California Water Boards. (2020). Notification level issuance: Contaminant(s): perfluorooctanesulfonic acid (PFOS). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfos_nl_issuance_jan2020.pdf.*

[135] California Water Boards. (2020). Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). State Water Resources Control Board. California Water Boards. *https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/PFOA_PFOS.html.*

[136] OEHHA. (2021). Public health goals: First public review draft: Perfluorooctanoic acid and perfluorooctane sulfonic acid in drinking water Office of Environmental Health Hazard Assessment. California Environmental Protection Agency. *https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.*

[137] California Water Boards. (2021). GeoTracker PFAS map. State Water Resources Control Board. California Water Boards. *https://geotracker.waterboards.ca.gov/map/pfas_map.*

[138] CDPHE. (2017). Site-specific groundwater standard: PFOA/PFOS. Colorado Department of Public Health & Environment. *https://www.colorado.gov/pacific/sites/default/files/WQ_GWStandard_PFOA_100417%20FINAL.pdf.*

[139] CDPHE. (2020). Policy 20–1. Policy for interpreting the narrative water quality: Standards for per- and polyfluoroalkyl substances (PFAS). Colorado Department of Public Health & Environment, Water Quality Control Commission. *https://drive.google.com/file/d/119FjO4GZVaJtw7YFvFqs9pmlwDhDO_eG/view.*

[140] Coleman, C. (2020). Colorado enacts arsenal of laws to stop ''forever chemicals''. Water Education Colorado. *https://www.watereducationcolorado.org/fresh-water-news/colorado-enacts-arsenal-of-laws-to-stop-forever-chemicals/.*

[141] CDPHE. (2020). Policy 20–1. Policy for interpreting the narrative water quality: Standards for per- and polyfluoroalkyl substances (PFAS). Colorado Department of Public Health & Environment, Water Quality Control Commission. *https://drive.google.com/file/d/119FjO4GZVaJtw7YFvFqs9pmlwDhDO_eG/view.*

[142] CT Interagency PFAS Task Force. (2019). PFAS action plan. Connecticut Interagency PFAS Task Force. Department of Public Health & Department of Energy and Environmental Protection. *https://portal.ct.gov/-/media/Office-of-the-Governor/News/20191101-CT-Interagency-PFAS-Task-Force-Action-Plan.pdf.*

[143] DNREC. (2021). Hazardous Substance Cleanup Act: Screening level table guidance. Delaware Department of Natural Resources and Environmental Control. *https://documents.dnrec.delaware.gov/dwhs/remediation/HSCA-Screening-Level-Table-Guidance.pdf.*

[144] DNREC. (2021). Sortable HSCA reporting level table (Excel). Delaware Department of Natural Resources and Environmental Control. *https://dnrec.alpha.delaware.gov/waste-hazardous/remediation/laws-regs-guidance/.*

[145] Florida DEP. (2020). Provisional PFOA and PFOS cleanup target levels & screening levels. Florida Department of Environmental Protection. *https://floridadep.gov/waste/district-business-support/documents/provisional-pfoa-and-pfos-cleanup-target-levels-screening.*

[146] Hawai'i DOH. (2020). Interim soil and water environmental action levels (EALs) for perfluoroalkyl and polyfluoroalkyl substances (PFASs). Hawaii State Department of Health. *https://health.hawaii.gov/heer/files/2020/12/PFASs-Techncal-Memo-HDOH-Dec-2020.pdf.*

numeric groundwater standard exists. The health-based guidance level for PFOA is 2 ppt and PFOS is 14 ppt.[147] Illinois EPA is conducting a statewide investigation into the prevalence and occurrence of PFAS in finished water at entry points to the distribution system representing 1,749 community water supplies across Illinois.[148]

• *Iowa:* The Iowa Department of Natural Resources issued Statewide Standards for PFOA and PFOS in 2016. The standards were set at 70 ppt for PFOA and PFOS for a protected groundwater source, and 50,000 ppt for PFOA and 1,000 ppt for PFOS for a non-protected groundwater source. Statewide standards for soil are 35 mg/kg for PFOA and 1.8 mg/kg for PFOS.[149]

• *Kansas:* The Kansas Department of Health and Environment, the Bureau of Environmental Remediation, and the Bureau of Water are working together to address PFAS in drinking water. The process involves the development of a statewide inventory and prioritization of potential PFAS sources. This information will be used to develop a public water supply monitoring program.[150]

• Maine's Department of Environmental Protection requires the testing of all sludge material licensed for land application in the state for PFAS (including PFOA and PFOS). The governor created a task force to mobilize state agencies and other stakeholders to review the prevalence of PFAS in Maine.[151] Maine Remedial Action Guidelines (RAGs) for Sites Contaminated with Hazardous Substances (2018) identified a water RAG of 400 ppt for PFOA and PFOS and a soils (residential) RAG of 1.7 mg/kg for PFOA and PFOS.[152] In June 2021, the Governor also signed an emergency resolution establishing an interim drinking water standard of 20 ppt for 6 PFAS. The resolution also requires that the Maine Department of Health and Human Services promulgate an MCL for PFAS by June 1, 2024.

• *Massachusetts:* In December 2019, the Massachusetts Department of Environmental Protection Office of Research and Standards reassessed the toxicity information for a subgroup of longer chain PFAS. They applied a revised reference dose (RfD) of 5×10^{-6} mg/kg-day to PFOA, PFOS, PFNA, PFHxS, PFHpA and perfluorodecanoic acid (PFDA). This reassessment resulted in an MCL of 20 ppt, promulgated in October 2020.[153] [154] Also, PFAS are considered to be hazardous material subject to the notification, assessment and cleanup requirements of the Massachusetts Waste Site Cleanup Program.[155]

• Michigan derived a toxicity value of 3.9×10^{-6} mg/kg-day for PFOA and 2.89×10^{-6} mg/kg-day for PFOS.[156] Michigan's public health drinking water MCLs are 8 ppt for PFOA and 16 ppt for PFOS, effective in August 2020. The Michigan PFAS Action Response Team has coordinated many actions across the state. Michigan Department of Health and Human Services has recommended people avoid contaminant-induced foam occurring on certain PFAS-contaminated surface water bodies and has initiated a PFAS Exposure and Health Study. The Michigan Department of Environment, Great Lakes, and Energy began a statewide initiative to test drinking water from all community water supplies for PFAS and has been testing watersheds. Do not eat advisories have also been issued for deer, fish, and other wildlife in certain parts of the state.[157] [158] [159] [160] [161] [162]

• Minnesota's Department of Health (MDH) identified RfDs of 1.8×10^{-5} milligram/kilogram-day (mg/kg-day) for PFOA, adopted as Rule in August 2018[163] and 3.1×10^{-6} mg/kg-day for PFOS, adopted as Rule in August 2020.[164] MDH developed guidance values in drinking water of 35 ppt for PFOA and 15 ppt for PFOS. The MDH is helping with drinking water well testing in certain areas of the state. Due to PFAS contamination in surface water bodies and levels of PFOS found in fish, the MDH has issued fish advisories for certain surface water bodies. Minnesota's Pollution Control Agency Toxics Reduction and Pollution Prevention program is working to reduce PFAS in firefighting foam, chrome plating, and food packaging, with related efforts in state and local government purchasing.[165]

---

[147] Illinois EPA. (2021). PFAS statewide health advisory. Illinois Environmental Protection Agency, Office of Toxicity Assessment. *https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-healthadvisory.aspx.*

[148] Illinois EPA. (2021). PFAS statewide investigation network: Community water supply sampling. Illinois Environmental Protection Agency, Office of Toxicity Assessment. *https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx.*

[149] Iowa DNR. (2021). Cumulative risk calculator: Statewide standards. Iowa Department of Natural Resources. *https://programs.iowadnr.gov/riskcalc/Home/statewidestandards.*

[150] KDHE. (2021). Per- and polyfluoroalkyl substances (PFAS). Kansas Department of Health and Environment. *https://www.kdheks.gov/pws/PFAS.htm.*

[151] Maine EPA. (2021). Per- and polyfluoroalkyl substances (PFAS). Maine Department of Environmental Protection Agency. *https://www.maine.gov/dep/spills/topics/pfas/index.html.*

[152] Maine DEP. (2018). Maine remedial action guidelines (RAGs) for sites contaminated with hazardous substances. Maine Department of Environmental Protection. *https://www.maine.gov/dep/spills/publications/guidance/rags/ME-Remedial-Action-Guidelines-10-19-18cc.pdf.*

[153] MassDEP. (2019). Technical support document: Per- and polyfluoroalkyl substances (PFAS): An updated subgroup approach to groundwater and drinking water values. Massachusetts Department of Environmental Protection. *https://www.mass.gov/files/documents/2019/12/27/PFAS%20TSD%202019-12-26%20FINAL.pdf.*

[154] MassDEP. (2020). 310 CMR 22: The Massachusetts drinking water regulations. Massachusetts Department of Environmental Protection, Drinking Water Program. *https://www.mass.gov/doc/310-cmr-2200-the-massachusetts-drinking-water-regulations/download.*

[155] MassDEP. (2019). Final PFAS-related revisions to the MCP. Massachusetts Department of Environmental Protection, Drinking Water Program. *https://www.mass.gov/lists/final-pfas-related-revisions-to-the-mcp-2019.*

[156] *Michigan.gov.* (2022). Health-based drinking water value recommendations for PFAS in Michigan. Michigan Department of Environment, Great Lakes, and Energy. Science Advisory Workgroup. *https://www.michigan.gov/documents/pfasresponse/Health-Based_Drinking_Water_Value_Recommendations_for_PFAS_in_Michigan_Report_659258_7.pdf.*

[157] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Investigations. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86511---,00.html.*

[158] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Investigations: Watershed investigations. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86511_95792---,00.html.*

[159] *Michigan.gov.* (2018). Michigan PFAS Action Response Team: Drinking water: Public drinking water: Statewide sampling initiative: Statewide testing initiative. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-95571_95577_95587---,00.html.*

[160] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: Fish and wildlife. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86512---,00.html.*

[161] *Michigan.gov.* (2021). Michigan PFAS Action Response Team: MPART: Press releases: MDHHS recommends Michiganders avoid foam on lakes and rivers. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-563821--y_2018,00.html.*

[162] *Michigan.gov.* (2020). Michigan PFAS Action Response Team: MPART: Press releases: MDHHS announces launch of new PFAS health study in impacted West Michigan communities. Michigan Department of Environment, Great Lakes, and Energy. *https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-544808--y_2018,00.html.*

[163] MDH. (2020). Toxicological summary for: Perfluorooctanoate. Minnesota Department of Health. *https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfoa.pdf.*

[164] MDH. (2020). Toxicological summary for: Perfluorooctane sulfonate. Minnesota Department of Health. *https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfos.pdf.*

[165] Minnesota PCA. (2022U.S.Navy). What is Minnesota doing about PFAS? Minnesota Pollution Control Agency. *https://www.pca.state.mn.us/waste/what-minnesota-doing-about-pfas.*

• Montana Department of Environmental Quality set a Groundwater Quality Standard for PFOA and PFOS, individually or combined, of 70 ppt in 2019.[166]

• Nevada Division of Environmental Protection identified basic comparison level values of 667 ppt for PFOA and PFOS in residential water and 1.56 mg/kg in residential soil.[167] Exceedance of a basic comparison level does not automatically trigger a response action but warrants further evaluation of health risks.[168]

• New Hampshire's Department of Environmental Services recommended RfDs of 6.1×10^{-6} mg/kg/day and 3.0×10^{-6} mg/kg/day for PFOA and PFOS, respectively, in June 2019.[169] New Hampshire has undertaken sampling for PFAS at water supplies (including drinking water sources), wastewater treatment plants, fire stations, landfills and contaminated waste sites to better understand the scope of contamination in the state. The New Hampshire Department of Environmental Services filed and finalized its rulemaking to establish MCLs for PFOA of 12 ppt and PFOS of 15 ppt, as well as 11 ppt for PFNA and 18 ppt for PFHxS.[170] The MCLs initially became effective on September 30, 2019. However, on December 31, 2019, the Merrimack County Superior Court issued a preliminary injunction barring enforcement of the MCLs. The New Hampshire legislature subsequently amended the New Hampshire Safe Drinking Water Act in July 2020 establishing the 4 PFAS MCLs.

• New Jersey Department of Environmental Protection (NJDEP) identified RfDs of 2×10^{-6} mg/kg-day for PFOA and 1.8×10^{-6} mg/kg-day for PFOS.[171] [172] On June 1, 2020, the NJDEP published a health based MCL for PFOA of 14 ppt and an MCL for PFOS of 13 ppt in the New Jersey Register. New Jersey previously adopted an MCL for PFNA of 13 ppt on September 4, 2018. New Jersey uses a risk assessment approach to protect for chronic drinking water exposure when setting MCLs. The NJDEP also adopted these same levels as formal groundwater quality standards for the purposes of site remediation activities and discharges to groundwater.[173] New Jersey has added PFNA, PFOA and PFOS to its hazardous substances list.

• New Mexico Environment Department issued Risk Assessment Guidance for Site Investigations and Remediation that identified preliminary screening levels of 70 ppt for PFOA, PFOS, and PFHxS, individually or combined, in drinking water and 1.56 mg/kg for PFOA, PFOS, and PFHxS in residential soil in 2019.[174]

• New York regulates PFOA and PFOS as hazardous substances. New York finalized regulations in 2017 that specify storage and registration requirements for Class B firefighting foams containing at least one percent by volume of one or more of four PFAS (including PFOA and PFOS) and prohibits the release of one pound or more of each into the environment during use. If a release meets or exceeds the one-pound threshold, it is considered a hazardous waste spill and must be reported, and cleanup may be required under the state's Superfund or Brownfields programs. In August 2020, New York adopted MCLs of 10 ppt for both PFOA and PFOS.[175] [176]

• North Carolina's Department of Environmental Quality determined an Interim Maximum Allowable Concentration for groundwater of 2,000 ppt for PFOA (table last updated in June 2021).[177]

• Ohio Environmental Protection Agency and Ohio Department of Health released a Polyfluoroalkyl Substances Action Plan for Drinking Water in 2019. Objectives included gathering sampling data, providing private water system owners with guidelines and resources to identify and respond to PFAS contamination, identifying resources to assist public water systems in the implementation of preventative and long-term measures to reduce PFAS-related risks, increasing awareness of PFAS and associated risks, ongoing engagement, and establishing Action Levels for drinking water systems in Ohio that are protective for human health. As part of this initiative, Ohio indicated that Action Levels of 70 ppt for PFOA and PFOS, singly or combined, would be established.[178]

• Oregon Department of Environmental Quality set initiation levels (ILs) for PFOA and PFOS of 24,000 ppt and 300,000 ppt, respectively (last amended in 2019). The rule indicated that ILs referred to concentrations in effluent, that, if exceeded, requires preparation of a pollutant reduction plan.[179] [180]

---

[166] Montana DEQ. (2019). Circular DEQ–7. Montana numeric water quality standards. Montana Department of Environmental Quality. *https://deq.mt.gov/files/Water/WQPB/Standards/PDF/DEQ7/DEQ-7.pdf*.

[167] NDEP. (2017). Nevada Division of Environmental Protection basic comparison levels. Nevada Division of Environmental Protection. *https://ndep.nv.gov/uploads/documents/july-2017-ndep-bcls.pdf*.

[168] Pontius, F. (2019). Regulation of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water: A comprehensive review. Water 11: 2003.

[169] NHDES. (2019). Technical background report for the June 2019 proposed maximum contaminant levels (MCLs) and ambient groundwater quality standards (AGQSs) for perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), and perfluorohexane sulfonic acid (PFHxS) and letter from Dr. Stephen M. Roberts, Ph.D. dated 6/25/2019—findings of peer review conducted on technical background report. New Hampshire Department of Environmental Services. *https://www4.des.state.nh.us/nh-pfas-investigation/wp-content/uploads/June-PFAS-MCL-Technical-Support-Document-FINAL.pdf*.

[170] NHDES. (2019). New Hampshire Code of Administrative Rules: Section Env-Dw 701.03—Units of measure for maximum contaminant levels (MCLs) and maximum contaminant level goals (MCLGs). New Hampshire Department of Environmental Services. *https://services.statescape.com/ssu/Regs/ss_8586370873779209008.pdf*.

[171] NJDWQI. (2017). Maximum contaminant level recommendation for perfluorooctanoic acid in drinking water basis and background. New Jersey Drinking Water Quality Institute. *https://www.nj.gov/dep/watersupply/pdf/pfoa-recommend.pdf*.

[172] NJDWQI. (2017). Appendix A. Health-based maximum contaminant level support document: perfluorooctanoic acid (PFOA). New Jersey Drinking Water Quality Institute. *https://www.nj.gov/dep/watersupply/pdf/pfoa-appendixa.pdf*.

[173] NJDEP. (2020). Ground water quality standards and maximum contaminant levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). New Jersey Department of Environmental Protection. *https://www.nj.gov/dep/rules/adoptions/adopt_20200601a.pdf*.

[174] NMED. (2019). Risk assessment guidance for site investigations and remediation. Volume I. Soil screening guidance for human health risk assessments. New Mexico Environment Department. *https://www.env.nm.gov/wp-content/uploads/sites/12/2016/11/Final-NMED-SSG-VOL-I_-Rev.2-6_19_19.pdf*.

[175] NYSDOH. (2020). Amendment of subpart 5–1 of title 10 NYCRR (maximum contaminant levels (MCLs)) notice of revised rulemaking. New York State Department of Health. *https://regs.health.ny.gov/sites/default/files/proposed-regulations/Maximum%20Contaminant%20Levels%20%28MCLs%29_0.pdf*.

[176] DEC. (2017). Fact sheet: Storage and use of Class B firefighting foams under new hazardous substance regulations. New York State Department of Environmental Conservation. *https://www.dec.ny.gov/docs/remediation_hudson_pdf/affffactsheet.pdf*.

[177] NCDEQ. (2021). Appendix #1: Interim maximum allowable concentrations (IMACs). North Carolina Department of Environmental Quality. *https://files.nc.gov/ncdeq/Water%20Quality/Planning/CSU/Ground%20Water/APPENDIX_I_IMAC_2-01-21.pdf*.

[178] *Ohio.gov*. (2019). Ohio per- and polyfluoroalkyl substances (PFAS) action plan for drinking water. Ohio Environmental Protection Agency. Ohio Department of Health. *https://content.govdelivery.com/attachments/OHOOD/2019/12/02/file_attachments/1335154/PFAS%20Action%20Plan%2012.02.19.pdf*.

[179] OAR. (2019). Division 45. Regulations pertaining to NPDES and WPCF permits 340–045–0100 Effect of a permit: Initiation level rule. Oregon Administrative Rule. *https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=256058*.

[180] OAR. ([2010]). OAR 340–045–0100: Table A—Persistent pollutants. Oregon Administrative Rule.

Continued

• Pennsylvania Department of Environmental Protection (PADEP) adopted a medium-specific concentration of 70 ppt in groundwater for PFOA and PFOS, individually or combined, based on EPA's 2016 LHAs. MSCs are 4.4 mg/kg for PFOA and PFOS in residential soil. PADEP has proposed rulemaking to incorporate groundwater and soil cleanup standards for PFOA, PFOS, and PFBS, and has initiated the process to set drinking water MCLs for PFOA and PFOS.[181]

• Rhode Island Department of Environmental Management (RIDEM) set Groundwater Quality Standards for PFOA and PFOS, individually or combined, of 70 ppt. RIDEM indicated that EPA's 2016 LHAs are used to determine the response to protect human health when these substances are detected in groundwater known or presumed to be suitable for drinking water use without treatment.[182]

• Texas has developed toxicity factors for PFOA and PFOS (using appropriate adjustments and uncertainty factors) for use at remediation sites. When combined with reasonable maximum long-term exposure assumptions for standard receptors (*e.g.,* residents, commercial/industrial workers) and multiple simultaneous routes of exposure (*e.g.,* incidental soil ingestion, dermal exposure), the Texas Commission on Environmental Quality believes these toxicity factors (*e.g.,* RfDs) will result in sufficiently protective environmental media (*e.g.,* soil) cleanup concentrations based on available data. Texas's RfDs for PFOA and PFOS are 1.2×10^{-05} and 2.3×10^{-05} mg/kg/day, respectively.[183] Tier 1 Protective Concentration Level (PCL) tables, released in January 2021, identified PCLs of 290 ppt for PFOA and 560 ppt for PFOS. PCLs are the default cleanup standards in the Texas Reduction Program.[184]

• Vermont's drinking water health advisory is 20 ppt for a combination of five (PFOA, PFOS, PFHxS, PFHpA and PFNA) compounds based on a combined risk assessment. Vermont has issued final rules amending a number of regulations pertaining to groundwater to set cleanup levels of 20 ppt for PFOA, PFOS, PFHxS, PFHpA and PFNA. These rules became effective on July 6, 2019. Vermont passed a law in 2019 requiring public water systems to monitor for PFAS.[185] [186] It also directed the Agency of Natural Resources to potentially regulate PFAS and report on various monitoring activities.[187]

• Washington is developing rule language to establish proposed state action levels (SALs) of 10 ppt for PFOA and 15 ppt for PFOS (also levels for 3 other PFAS). SALs are levels set for long-term daily drinking water to protect human health; systems that exceed SALs would be required to notify their customers.[188]

• Wisconsin identified a toxicity value (acceptable daily intake) of 2×10^{-6} mg/kg-day for PFOA and recommended the ATSDR value of 2×10^{-6} mg/kg-day for PFOS.[189] The Wisconsin Department of Health Services has sent to Wisconsin Department of Natural Resources recommended groundwater standards of 20 ppt for PFOA and PFOS individually and combined.[190] The Wisconsin PFAS Action Council has developed statewide initiatives to address PFAS in Wisconsin. The council led the development of a comprehensive Wisconsin PFAS Action Plan that will serve as a roadmap for how state agencies will address these emerging chemicals.[191]

D. Enforcement

Enforcement actions, both by states and EPA, have been taken to mitigate risks from PFOA and PFOS. To date, EPA has addressed PFAS in 16 cases using a variety of enforcement tools under the Safe Drinking Water Act (SDWA), TSCA, RCRA, and CERCLA,[192] as well as overseeing PFAS response actions by Federal agencies at National Priorities List sites.

For example, in 2002 the EPA entered into an emergency administrative order on consent under SDWA with E. I. du Pont de Nemours and Company. DuPont agreed to provide alternative drinking water or treatment for public or private water users living near the Washington Works facility in Washington, West Virginia, if the level of PFOA detected in their drinking water was greater than the PFOA screening level established by a C–8 Assessment of Toxicity team. The C–8 Assessment team was formed pursuant to a state order and established the screening level for PFOA at 150,000 ppt. In 2006, after the science on health effects of PFOA evolved, the EPA entered into a second emergency administrative order under SDWA with DuPont that replaced the 2002 order and established a site-specific action level equal to or greater than 500 ppt.[193]

In 2009, after EPA scientists established a provisional health advisory for PFOA of 400 ppt to address short-term exposure to PFOA, EPA entered into a third emergency administrative order under the SDWA with DuPont that replaced the 2006 order and lowered the allowable concentration of PFOA in drinking water from 500 ppt to 400 ppt in communities near the facility. The provisional health advisory for PFOA

https://secure.sos.state.or.us/oard/viewAttachment.action;JSESSIONID_OARD=kx0KPdcNidFhJyQctRxEOn3fLasJ_U1SHXoqfYc80w8WtuLnSAlk!-888754201?ruleVrsnRsn=256058.

[181] Schena, R. (2021). New Pennsylvania PFOS and PFOA cleanup standards reach final major regulatory hurdle. JD Supra. *https://www.jdsupra.com/legalnews/new-pennsylvania-pfos-and-pfoa-cleanup-3985880/.*

[182] RIDEM. (2017). Rhode Island Department of Environmental Management determination of a groundwater quality standard for: Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Rhode Island Department of Environmental Management. *https://www.dem.ri.gov/programs/benviron/water/quality/pdf/pfoa.pdf.*

[183] TCEQ. (2016). Perfluoro compounds (PFCs): Various CASRN numbers. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/assets/public/implementation/tox/evaluations/pfcs.pdf.*

[184] TCEQ. (2021). TRRP Protective concentration levels. Texas Commission on Environmental Quality. *https://www.tceq.texas.gov/remediation/trrp/trrppcls.html.*

[185] HealthVermont. (2018). Memorandum: Drinking water health advisory for five PFAS (per- and polyfluorinated alkyl substances). Vermont Department of Health. *https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_DW_PFAS_HealthAdvisory.pdf.*

[186] Vermont ANR. (2019). Chapter 12 of the environmental protection rules: Groundwater protection rule and strategy. Vermont Agency of Natural Resources. *https://dec.vermont.gov/sites/dec/files/dwgwp/DW/2019.07.06%20-%20GWPRS.pdf.*

[187] Vermont ANR. (2019). ACT 21 (S. 49): Vermont 2019 PFAS law factsheet. Vermont Agency of Natural Resources. *https://dec.vermont.gov/sites/dec/files/PFAS/Docs/Act21-2019-VT-PFAS-Law-Factsheet.pdf.*

[188] WA DOH. (2021). PFAS and drinking water: What is a state action level? Washington State Department of Health. *https://www.doh.wa.gov/CommunityandEnvironment/Contaminants/PFAS#StateActionLevels.*

[189] Wisconsin DHS. (2019). Recommended public health groundwater quality standards: Scientific support documents for cycle 10 substances. Wisconsin Department of Health Services. *https://www.dhs.wisconsin.gov/publications/p02434v.pdf.*

[190] Wisconsin DHS. (2021). Per- and polyfluoroalkyl substances (PFAS). Wisconsin Department of Health Services. *https://www.dhs.wisconsin.gov/chemical/pfas.htm.*

[191] WisPAC. (2020). Wisconsin PFAS Action Plan. Wisconsin PFAS Action Council. Department of Natural Resources. *https://dnr.wisconsin.gov/topic/Contaminants/ActionPlan.html.*

[192] Where PFAS are commingled with CERCLA hazardous substances, EPA can require PRPs to address the PFAS. Additionally, CERCLA Section 120 federal facility agreements for federal facilities listed on the NPL require federal agencies to investigate and clean up hazardous substances, pollutants and contaminants which includes PFAS.

[193] U.S. EPA. (2021). E.I. DuPont de Nemours and Company PFOA settlements. U.S. Environmental Protection Agency. *https://www.epa.gov/enforcement/ei-dupont-de-nemours-and-company-pfoa-settlements.*

was based on available science at that time.[194]

In 2017, EPA issued an amendment to the 2009 emergency administrative order with DuPont by adding The Chemours Company as a respondent and lowering the allowable concentration of PFOA in drinking water from 400 ppt to 70 ppt in communities near the facility. The amendment, issued on May 19, 2016, was based upon current science, changed circumstances, site-specific information, and EPA's health advisories for PFOA and PFOS.[195]

Designating PFOA and PFOS as CERCLA hazardous substances will allow EPA to use its CERCLA enforcement authorities, in appropriate circumstances and where relevant statutory elements are met, which could allow a transfer of the cost-burden of response activities at privately owned sites from the taxpayers/fund to potentially responsible parties.

E. International Actions

PFAS, including PFOA and PFOS, are subject to international treaties and individual country regulations on their production, use, and release to the environment.

PFOA is identified by the United Nations Environment Programme (UNEP) as ''a substance of very high concern with a persistent, bioaccumulative and toxic structure for the environment and living organisms'' and is listed under Annex A of the Stockholm convention.[196] (Parties must take measures to eliminate production and use of the chemicals listed in Annex A.)

In November 2017, the Persistent Organic Pollutants Review Committee adopted a risk management evaluation for PFOA, its salts and PFOA-related compounds, defined as ''any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety $(C_7F_{15})C$ as one of the structural elements, for example: (i) Polymers with ≥C8 based perfluoroalkyl side chains; 8:2 fluorotelomer compounds; and (iii) 10:2 fluorotelomer compounds''.[197] [198] In 2019, at the 9th Conference of Parties (COP–9) meeting, the Stockholm Convention agreed to a global ban on PFOA and some related compounds for criteria including health effects such as kidney cancer, testicular cancer, thyroid disease, ulcerative colitis and pregnancy-induced hypertension. This action also included five-year exemptions for use in semiconductor manufacturing, firefighting foams, worker-safety textiles, photographic coatings for films and medical devices. While a signatory to the Stockholm Convention, the U.S. has not ratified and is therefore not a Party to the convention however; additional exemptions were requested by China, Iran and the European Union.[199]

PFOS, along with its salts and precursor POSF have been classified as a persistent, highly bioaccumulative organic pollutant and listed under Annex B of the Stockholm Convention.[200] At the 2009 Stockholm Convention COP–4 meeting, parties to the convention restricted PFOS production and use, but also included exemptions. The 2019 COP–9 meeting tightened PFOA and PFOS restrictions, but left an exemption for the pesticide sulfluramid, which is known to degrade into PFOS and PFOA.[201] [202] This pesticide is no longer registered for use in the United States.

The European Union (EU) has taken steps to regulate PFOA, its salts and related substances in a wide range of products.[203] PFOA and APFO are also required to be classified, labelled, and packaged under regulation EC No 1272/2008 [204] and there is a ban on placing these chemicals on the market as substances, constituents of other substances, or in mixtures for supply to the general public. PFNA and PFDA have been proposed for similar classification and labelling by Sweden.

In July 2020, the European Food Safety Authority [205] modified its 2018 decision to set safety levels for PFOA and PFOS to include PFNA and PFHxS, based on their observed human bioaccumulation and toxicity. A combined safety threshold or group tolerable weekly limit in food and water of 4.4 nanograms/kilogram of body weight was set for these four PFAS.

Because there are thousands of PFAS widespread in the environment and substance-by-substance risk assessments, environmental monitoring and regulation would be extremely lengthy and resource-intensive, an alternative approach has been proposed to regulate PFAS as a class, or as subgroups, based on toxicity or chemical similarities. The agreement by the European Parliament and the

[194] Ibid.

[195] U.S. EPA. (2017). News releases from Region 03 EPA amends drinking water order to DuPont. U.S. Environmental Protection Agency. *https://archive.epa.gov/epa/newsreleases/epa-amends-drinking-water-order-dupont.html*.

[196] UNEP. (2019). POPs chemicals Mandeeps. Stockholm Convention on Persistent Organic Pollutants. United Nations Environment Programme. *https://chm.pops.int/DNNADMIN/DataEntry/MandeepsHiddenModules/POPsChemicalsMandeeps/tabid/754/Default.aspx*.

[197] UNEP. (2017). Report of the Persistent Organic Pollutants Review Committee on the work of its thirteenth meeting: Addendum: Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335–67–1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.13/7/Add.2). United Nations Environment Programme. *https://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC13/MeetingDocuments/tabid/6024/Default.aspx/*.

[198] UNEP. (2018). Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting—Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/POPRC.14/6/Add.2). United Nations Environment Programme. *https://chm.pops.int/theconvention/popsreviewcommittee/meetings/poprc14/overview/tabid/7398/default.aspx*.

[199] UNEP. (2019). Recommendation by the Persistent Organic Pollutants Review Committee to list perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds in Annex A to the Convention and draft text of the proposed amendment. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/COP.9/14). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx*.

[200] UNEP. (2019). POPs chemicals Mandeeps. Stockholm Convention on Persistent Organic Pollutants. United Nations Environment Programme. *https://chm.pops.int/DNNADMIN/DataEntry/MandeepsHiddenModules/POPsChemicalsMandeeps/tabid/754/Default.aspx*.

[201] UNEP. (2009). Listing of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride. Stockholm Convention on Persistent Organic Pollutants. (UNEP–POPS–COP.4–SC–4–17). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP4/COP4Documents/tabid/531/Agg3187_SelectTab/4/Default.aspx*.

[202] UNEP. (2019). Evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention. Stockholm Convention on Persistent Organic Pollutants. (UNEP/POPS/COP.9/7). United Nations Environment Programme. *https://chm.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP9/tabid/7521/Default.aspx*.

[203] EU. (2017). Commission regulation (EU) 2017/1000 of 13 June 2017 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. (Official J Eur Union L150/14). European Union. *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32017R1000*.

[204] EU. (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. (Official J Eur Union L353/1). European Union. *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272*.

[205] EFSA. (2020). Risk to human health related to the presence of perfluoroalkyl substances in food. EFSA Journal 18: e06223. *https://www.ncbi.nlm.nih.gov/pubmed/32994824*.

Council in December 2019 on the recast of the Drinking Water Directive includes a limit of 0.5 micrograms per liter for all PFAS.[206] In December 2020, the European Parliament formally adopted the revised Drinking Water Directive.[207] Based on the widespread occurrence of PFAS in the environment and their risk properties, in June 2019 the European Council of Ministers called for an action plan to eliminate all non-essential uses of PFAS.[208]

A number of countries have issued standards and guidance values for PFOA, PFOS, and other PFAS individually or cumulatively. These are summarized below.

Australia and New Zealand [209]—The Food Standards Australia New Zealand (FSANZ), a statutory authority in the Australian Government health portfolio, and the National Medical Research Council have developed health-based guidance values for PFOA, PFOS, and PFHxS for exposure from food, drinking water and surface water used for recreation. The guidance values give tolerable daily intake (TDI) for lifetime exposure levels from food or drinking water that will not result in significant risk to human health. Based on the TDI, FSANZ recommended tolerable daily intake and issued drinking water and recreational water guideline values for use in site investigations in Australia. TDI were derived from animal studies and pharmacokinetic modeling used to extrapolate to humans. For PFHxS, FSANZ concluded that the available data were insufficient to develop a TDI and that the PFOS TDI should be applied to PFHxS and a combined concentration of PFOS plus PFHxS should be used to evaluate exposure.

Health based guidance value	Total PFOS+PFHxS	PFOA
Tolerable daily intake (nanograms/kilogram of body weight per day)	20	160
Drinking water quality guideline value (nanograms per liter)	70	560
Recreational water quality guideline value (nanograms per liter)	2,000	10,000

Canada—PFOA, its salts and precursors, as well as long-chain perfluorocarboxylic acids, their salts and precursors were assessed in 2012. These substances are prohibited for import and use with a limited number of exemptions under the *Prohibition of Certain Toxic Substances Regulations, 2012.* In 2018 additional proposed amendments to the Canadian Environmental Protection Act, 1999, to regulate additional PFAS were postponed to late 2021. The proposed amendments include PFOS, its salts and precursors that contain one of the following groups: $C_8F_{17}SO_2$, $C_8F_{17}SO_3$ or $C_8F_{17}SO_2N$ (PFOS), PFOA and its salts and precursors. It also includes all longer chain perfluorocarboxylic acids having the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \leq n \leq 20$, their salts and precursors.[210] [211]

Guidelines for Canadian Drinking Water Quality set the maximum acceptable concentration (MAC) for PFOA in drinking water at 200 ppt [212] and PFOS in drinking water at 600 ppt.[213] These MACs are based on exposure to individual chemicals. Because the toxicological effects of PFOA and PFOS are additive they should be evaluated together, and the ratio of the observed concentration for PFOS to its MAC plus the ratio of the observed concentration for PFOA to its MAC should be below 1 for drinking water to considered safe.[214] [215] For other PFAS with a more limited database, drinking water screening values were developed.

Peoples Republic of China—The ''Industrial Recon-structuring Guide Directory'' [216] restricted the production of PFOS and PFOA. In 2014, the Ministry of Environmental Protection announcement No. [2014]21, banned ''production, transportation, application, imports and exports of PFOS, its salts, and POSF, except for specific exemptions and acceptable use.''

Denmark—Based on toxicity the Danish Environmental Protection Agency [217] has identified health-based criteria or limit values for drinking water, groundwater used for drinking water and soil. Criteria or limit values for drinking water and groundwater used for drinking water are 100 nanograms per liter for PFOS and/or PFOSA (a PFOS precursor) and 300

[206] EEA. (2019). Emerging chemical risks in Europe—'PFAS'. European Environment Agency. European Union. *https://www.eea.europa.eu/ds_resolveuid/a8da291194084d2eaa5bb0a9147e793a*.

[207] EC. (2020). Review of the drinking water directive. European Commission. *https://ec.europa.eu/environment/water/water-drink/review_en.html*.

[208] EU. (2019). Outcome of proceedings: Subject: Towards a sustainable chemicals policy strategy of the Union—Council conclusions. Council of the European Union. *https://www.consilium.europa.eu/media/40042/st10713-en19.pdf*.

[209] Australian Government. (2019). Health based guidance values for PFAS. Australian Government, Department of Health. *https://www1.health.gov.au/internet/main/publishing.nsf/Content/2200FE086D480353CA2580C900817CDC/$File/HBGV-Factsheet-20190911.pdf*.

[210] Environment and Climate Change Canada. (2021). Toxic substances list: long-chain perfluorocarboxylic acids. Environment and Climate Change Canada, Government of Canada. *https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/long-chain-perfluorocarboxylic-acids.html*.

[211] Environment and Climate Change Canada. (2021). Toxic substances list: PFOS. Environment and Climate Change Canada, Government of Canada. *https://www.canada.ca/en/environment-climate-change/services/management-toxic-substances/list-canadian-environmental-protection-act/perfluorooctane-sulfonate.html*.

[212] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctanoic acid (PFOA). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-technical-document-perfluorooctanoic-acid/document.html*.

[213] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctane sulfonate (PFOS). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/document.html*.

[214] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctanoic acid (PFOA). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-technical-document-perfluorooctanoic-acid/document.html*.

[215] Health Canada. (2018). Guidelines for Canadian drinking water quality: Guideline technical document—perfluorooctane sulfonate (PFOS). Health Canada. Minister of Health. *https://www.canada.ca/en/health-canada/services/publications/healthy-living/guidelines-canadian-drinking-water-quality-guideline-technical-document-perfluorooctane-sulfonate/document.html*.

[216] OECD. (2021). Portal on per and poly fluorinated chemicals: Country information: People's Republic of China. Organisation for Economic Co-operation and Development. *https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/china.htm*.

[217] Danish Ministry of the Environment. (2015). Perfluoroalkylated substances: PFOA, PFOS and PFOSA: Evaluation of health hazards and proposal of a health based quality criterion for drinking water, soil and ground water. (Environmental project No. 1665). Copenhagen, Denmark: The Danish Environmental Protection Agency. *https://www2.mst.dk/Udgiv/publications/2015/04/978-87-93283-01-5.pdf*.

nanograms per liter for PFOA. For cumulative exposure the ratio of the sum of concentration/limit value ratios for PFOA, PFOS and PFOSA should be below 1.

The health-based criteria or limit value for soil is 390 micrograms per kilogram for PFOS and PFOSA and 1,300 micrograms per kilogram for PFOA and its salts. Cumulatively the sum of concentration/limit value ratios for PFOA, PFOS and PFOSA should be below 1.[218]

The Danish Ministry of the Environment and Food [219] banned food contact paper and cardboard in which per and polyfluoro chemicals, including PFOA and PFOS and their salts and precursors, have been used unless they incorporate a barrier to prevent migration into food.

Japan—In 2010, Japan designated PFOS, its salts, and POSF as Class I Specified Chemical Substances following their addition to the Stockholm Convention on Persistent to Organic Pollutants Annex B regulating manufacture, use, export, and import of PFOA and its salts.[220]

Norway—Norway listed PFOA and PFOS on its national list of priority substances [221] based on monitoring data that showed high levels of these substances in the environment as well as their toxicological profiles. In 2014, Norway banned manufacturing, production, import and retail of consumer products containing PFOA.[222]

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the OMB for review. While EPA is not considering costs in its hazardous substance designation decisions in this proposed rule, and despite that there is still significant uncertainty and lack of data as discussed in the economic analysis (EA), OMB designated this proposed rulemaking as an economically significant action. Any changes made in response to the OMB recommendations have been documented in the docket. Although CERCLA section 102(a) precludes EPA from taking cost into account in the designation of a hazardous substance, to inform the public, EPA prepared an EA of the potential costs, benefits, and impacts associated with this action. This analysis, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* is available in the docket for this action. The EA includes request for comments on several topics that EPA does not currently have robust information about. Please see Section ES–5 of the EA for specific details.

If finalized, this proposed CERCLA designation is estimated to have a quantifiable direct annual social cost of approximately $370,000 from reporting releases at or above the RQ. Additional, unquantifiable future costs may occur when Federal agencies sell or transfer real property where PFOA or PFOS was stored, released or disposed of as specified by CERCLA section 120(h). There is also the direct effect resulting in an obligation of DOT to list and regulate CERCLA-designated hazardous substances as hazardous materials under the Hazardous Materials Transportation Act (see CERCLA Section 306(a)). EPA estimates these incremental costs associated with the DOT rulemaking as zero or negligible. This action's direct benefits from release reporting include improved quality of information providing a more comprehensive understanding of the number and location of PFOA and PFOS releases meeting or exceeding the RQ. An important benefit of this information is that it may lead to more efficient property and capital markets. Another potential direct benefit from the proposed reporting requirement is better waste management and/or treatment by facilities handling PFOA or PFOS. Greater transparency provided by release reporting can lead to fewer releases to the environment and thus to health benefits associated with avoided exposure.

Designating PFOA and PFOS as hazardous substances may also have indirect, indeterminate impacts associated with potential increases in the speed of response activity and in the total number of response actions taken to address PFOA and PFOS releases. Both potential increases may lead to health benefits associated with avoided risks. Other indirect effects may be experienced as a result of the movement forward in time of assessment and cleanup costs. The proposed designation would also improve the Agency's ability to transfer response costs from the public to polluters contingent upon specific statutory requirements being met and discretionary actions by EPA. These indirect costs, benefits, and transfers cannot be quantified due to significant uncertainties about each. The full discussion of these impacts can be found in the EA.

B. Paperwork Reduction Act

The information collection activities in this proposed rule have been submitted for approval to the OMB under the Paperwork Reduction Act. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2708.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

If finalized, the designation of PFOA and PFOS, and their salts and structural isomers, as hazardous substances would require any person in charge of a vessel or facility that identifies a release of one pound or more within a 24-hour period of these substances to report the release to the NRC under section 103 of CERCLA and to the SERC (or TERC) and LEPC (or TEPC) under section 304 of EPCRA. The implementing regulations of CERCLA section 103 and EPCRA section 304 are codified at 40 CFR parts 302 and 355, respectively.

Respondents/affected entities: Any person in charge of a vessel or facility from which there is a release of PFOA or PFOS and their salts and structural isomers, equal to or greater than the RQ of one pound within 24 hours.

Respondent's obligation to respond: Mandatory under section 103 of CERCLA and section 304 of EPCRA.

Estimated number of respondents: From 0 to 660 releases per year.

Frequency of response: Varies.

[218] Ibid.

[219] *PackingLaw.com.* (2020). Denmark's PFAS ban in paper and cardboard effective in July 2020. Keller and Heckman LLP. *https://www.packaginglaw.com/news/denmarks-pfas-ban-paper-and-cardboard-effective-july-2020.*

[220] Ministry of the Environment of Japan. (2013). Summary of the guideline on the treatment of wastes containing perfluorooctane sulfonic acid (PFOS), and its salts in Japan. Ministry of the Environment of Japan. *https://www.env.go.jp/en/focus/docs/files/201304-89.pdf.*

[221] OECD. (2021). Portal on per and poly fluorinated chemicals: Country information: Norway. Organisation for Economic Co-operation and Development. *https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/countryinformation/norway.htm.*

[222] UL. (2013). Norway introduces restrictions on PFOA. UL, LLC. *https://www.ul.com/news/norway-introduces-restrictions-pfoa.*

Total estimated burden: 6,415 hours (per year) maximum. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $370,000 (per year) maximum, includes $3,503 annualized operation and maintenance costs (and no capital costs).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 6, 2022. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are: (1) producers and importers of PFOA and PFOS, (2) producers and users of PFOA or PFOS-containing articles, and (3) waste management and wastewater facilities. The Agency has estimated that there may be up to 660 reported releases of PFOA or PFOS in any one year and that an indeterminate number, but small percentage, of the annual reports will be submitted by small entities. The estimated cost of $561 to report a release of PFOA or PFOS is not greater than 1% of the annual revenues per small entity in any impacted industry. Details of this analysis are presented in the *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances.* We have therefore concluded that this action will not have a significant regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action is expected to result in reporting costs of $561 per release that meets or exceeds the RQ, and the estimated annual cost of the proposed rule is not expected to exceed $370,000 per year.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 because it does not have substantial direct effects on one or more Tribal Nations, on the relationship between the Federal Government and Tribal Nations, or on the distribution of power and responsibilities between the Federal Government and Tribal Nations. EPA does not expect that it would result in any adverse impacts on tribal entities. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation with Tribal Nations, the EPA intends to consult with and request comments from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action, which proposes to designate PFOA and PFOS as hazardous substances, does not itself address environmental health or safety risks. Beyond the requirements of E.O. 13045, EPA's *2021 Policy on Children's Health* (October 5, 2021)[223] requires EPA to consider early life exposures and lifelong health consistently and explicitly in all human health decisions. The EPA believes that the environmental health or safety risk posed by exposure to PFOA and/or PFOS may have a disproportionate effect on children. A discussion of health and risk assessments related to PFOA and PFOS, including developmental and reproductive health effects, are contained in EPA's Health Effects Support Documents for PFOA and PFOS (2016).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action proposes to designate PFOA and PFOS as hazardous substances, and thus, does not involve the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA is unable to determine if this action does or does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

Several key demographic categories were analyzed relative to facilities with known historical use and/or releases of PFOA and PFOS.[224] Because the location of future releases of PFAS is uncertain, this analysis considers populations around facilities in sectors associated with widespread historical uses and releases of PFAS as proxies for facilities that may have future releases of the PFAS considered in the proposed rule. This analysis examines the following site types as proxies for facilities that are known to have commonly used PFAS:

- Operating Department of Defense (DOD) facilities
- Operating U.S. airports and airfields

[223] U.S. EPA. (2021). The administrator: 2021 policy on children's health. Washington, DC: U.S. Environmental Protection Agency. *https://www.epa.gov/system/files/documents/2021-10/2021-policy-on-childrens-health.pdf.*

[224] U.S. EPA. ([2021]). Assessment of the potential costs and other impacts of the proposed rulemaking to designate perfluorooctanoic acid and perfluorooctanesulfonic acid as hazardous substances. U.S. Environmental Protection Agency.

- Plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA,
- 2020 PFOS and PFOA releases reported to EPA's Toxic Release Inventory (TRI)

On average, airports across the U.S. are surrounded by populations that reflect national averages in relevant demographic categories. Large airports, however, are more likely to be surrounded by minority and low-income populations than medium or small airports. Some DOD sites are surrounded by populations with higher concentrations of minority and low-income residents, but the majority of these sites are below the national averages for these metrics. In contrast, areas around plastics material and resin manufacturer sites and/or sites reporting releases to TRI, on average, are in areas with higher concentrations of minority residents and households experiencing poverty than the U.S. averages for these demographics, suggesting that releases related to manufacturing facilities could have environmental justice implications. A complete discussion of the analysis behind these findings is available in Section 4.3 of the EA accompanying this rulemaking. These findings, combined with the uncertainty surrounding the location of future releases, are indicative of potential impacts but do not provide a clear indication of the type of disparities related to potential exposure to PFAS. Consistent with the priorities outlined in Executive Orders 12898 [225] and 14008,[226] it is unclear whether this proposed regulation will have a significant impact on disadvantaged populations or communities with environmental justice (EJ) concerns relative to other communities. While the locations that may report releases are unknown, to the extent that these proxy locations are representative of likely reporting locations, this screening analysis suggests that the reporting required under the rule may provide better information to nearby populations potentially at risk of exposure, including communities with EJ concerns. To the extent that PFAS releases are consistent with the broader releases reported to TRI and typically involve disposal or manufacturing sites, demographic data around plastics material and resin manufacturer sites and historical releases may be a more reliable predictor of the type of community potentially affected by this proposed rulemaking. Specific site conditions and demographic patterns may become clear as reporting occurs following completion of a final rule. Once available, this information would improve EPA's ability to examine disparate impacts on EJ communities. This improved information would not increase risk for communities with EJ concerns and may improve the speed and design of remediation. EPA is committed to minimizing and/or eliminating existing barriers and burdens that communities with EJ concerns may encounter related to accessing data and information collected as a result of this rulemaking, if finalized. EPA seeks comment on strategies to improve access to the reporting data expected to be collected, if designation of PFOA and PFOS as hazardous substances is finalized, for communities with environmental justice concerns.

Further, the documentation for this decision is contained in the following sections in the preamble to this action: II.C., VI.A. and B. These sections explain that the designation of PFOA and PFOS as hazardous substances, if finalized, and the required reporting and notification requirements, will result in more information about the location and extent of releases. This improved information does not increase risk or result in any adverse environmental justice impacts.

List of Subjects in 40 CFR Part 302

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Michael S. Regan,
Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 302 as follows:

PART 302—DESIGNATION, REPORTABLE QUANTITIES, AND NOTIFICATION

■ 1. The authority citation for part 302 continues to read as follows:

Authority: 33 U.S.C. 1251 *et. seq.,* 42 U.S.C. 9601, *et seq.,* 42 U.S.C. 9602, 42 U.S.C. 9603.

■ 2. Amend § 302.4 by:

■ a. Revising in paragraph (b) the Note II to Table;

■ b. Adding in the Table—List of Hazardous Substances and Reportable Quantities in alphabetical order the following new entries for ''Perfluorooctanesulfonic acid, salts, & structural isomers'' and ''Perfluorooctanoic acid, & salts, & structural isomers'';

■ c. Adding in Appendix A—Sequential CAS Registry Number List of CERCLA Hazardous Substances in numerical order the new entries for ''335–67–1'' and ''1763–23–1''.

The revisions read as follows:

§ 302.4 [Amended]

* * * * *

(b) * * *

Note II to Table 302.4

Hazardous substances are given a Statutory Code based on their statutory source. The ''Statutory Code'' column indicates the statutory source for designating each substance as a CERCLA hazardous substance. Statutory Code ''1'' indicates a Clean Water Act (CWA) Hazardous Substance. Statutory Code ''2'' indicates a CWA Toxic Pollutant. Statutory Code ''3'' indicates a CAA HAP. Statutory Code ''4'' indicates Resource Conservation and Recovery Act (RCRA) Hazardous Wastes. Statutory Code ''5'' indicates a hazardous substance designated under section 102(a) of CERCLA. The ''RCRA waste No.'' column provides the waste identification numbers assigned by RCRA regulations. The ''Final RQ [pounds (kg)]'' column provides the reportable quantity for each hazardous substance in pounds and kilograms.

* * * * *

[225] The White House. (1994). Presidential documents: Executive order 12898 of February 11, 1994: Federal actions to address environmental justice in minority populations and low-income populations. **Federal Register** 59: 7629. *https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf.*

[226] *WH.gov.* (2021). Executive order on tackling the climate crisis at home and abroad. Washington, DC: The White House. *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/executive-order-on-tackling-the-climate-crisis-at-home-and-abroad/.*

TABLE 302.4—LIST OF HAZARDOUS SUBSTANCES AND REPORTABLE QUANTITIES
[All comments/notes are located at the end of this table]

Hazardous substance	CASRN	Statutory code †	RCRA waste No.	Final RQ [pounds (kg)]
* * * * * * *				
Perfluorooctanesulfonic acid, & salts, & structural isomers	1763–23–1	5		## (0.454)
Perfluorooctanoic acid, & salts, & structural isomers	335–67–1	5		## (0.454)
* * * * * * *				

* * * * *

Appendix A to § 302.4—Sequential CAS Registry Number List of CERCLA Hazardous Substances

CASRN	Hazardous substance
335–67–1	Perfluorooctanoic acid, & salts, & structural isomers.
1763–23–1	Perfluorooctanesulfonic acid, & salts, & structural isomers.

[FR Doc. 2022–18657 Filed 9–2–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 2

[DOI–2022–0007; 223D0102DM, DLSN00000.000000, DS65100000, DX.65101]

RIN 1090–AB16

Privacy Act Regulations; Exemption for the Personnel Security Program Files System

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of the Interior (DOI) is proposing to amend its regulations to exempt certain records in the INTERIOR/DOI–45, Personnel Security Program Files, system of records from one or more provisions of the Privacy Act of 1974 because of criminal, civil, and administrative law enforcement requirements.

DATES: Submit comments on or before November 7, 2022.

ADDRESSES: You may submit comments, identified by docket number [DOI–2022–0007] or [Regulatory Information Number (RIN) 1090–AB16], by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.

• *Email: DOI_Privacy@ios.doi.gov.* Include docket number [DOI–2022–0007] or RIN 1090–AB16 in the subject line of the message.

• *U.S. Mail or Hand-Delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2022–0007] or RIN 1090–AB16 for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240, *DOI_Privacy@ios.doi.gov* or (202) 208–1605.

SUPPLEMENTARY INFORMATION:

Background

The Privacy Act of 1974, as amended, 5 U.S.C. 552a, governs the means by which the U.S. Government collects, maintains, uses and disseminates personally identifiable information. The Privacy Act applies to information about individuals that is maintained in a ''system of records.'' A system of records is a group of any records under the control of an agency from which information about an individual is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. See 5 U.S.C. 552a(a)(4) and (5).

Individuals may request access to records containing information about themselves under the Privacy Act, 5 U.S.C. 552a(b), (c) and (d). However, the Privacy Act authorizes Federal agencies to exempt systems of records from access by individuals under certain circumstances, such as where the access or disclosure of such information would impede national security or law enforcement efforts. Exemptions from Privacy Act provisions must be established by regulation, 5 U.S.C. 552a(j) and (k).

The DOI Office of Law Enforcement and Security (OLES) maintains the INTERIOR/DOI–45, Personnel Security Program Files, system of records. This system supports the DOI bureau and office Personnel Security Program functions to determine suitability, eligibility, and fitness for service of applicants for Federal employment and contract positions who require access to Departmental facilities and information systems and networks. The system also helps OLES manage a National Security Program to document and support decisions regarding clearance access to classified information and implement provisions that apply to Federal employees and contractors who access classified information or materials and participate in classified activities that impact national security, and ensure the safety, storage of classified information and security of Departmental facilities, information systems and networks, occupants, and users.

The Personnel Security Program Files system will contain records created and managed by DOI bureaus and offices to support personnel security activities and document evaluations and decisions regarding suitability, eligibility, and fitness for service of applicants for Federal employment and contract positions to the extent necessary to manage secure access to Departmental facilities, information systems and networks, and to manage access to classified information and reciprocity. These records may include information about individuals related to possible violations of Federal laws and

****E.O. 12866/13563 Review - Draft – Deliberative – Do Not Cite, Quote, or Release****

EO12866_PFOA-PFOS Designation 2050-AH09 Propose EA_20190920

ECONOMIC ASSESSMENT OF THE POTENTIAL COSTS AND OTHER IMPACTS OF THE PROPOSED RULEMAKING TO DESIGNATE PERFLUOROOCTANOIC ACID (PFOA) AND PERFLUOROOCTANESULFONIC ACID (PFOS) AS HAZARDOUS SUBSTANCES

Office of Land and Emergency Management
U.S. Environmental Protection Agency, 1200 Pennsylvania Ave NW,
Washington, DC 20460

August 2022

[This page intentionally left blank.]

ACRONYMS AND TERMS

AFFF	–	Aqueous Film Forming Foams
CERCLA	–	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	–	Code of Federal Regulations
CWA	–	Clean Water Act
DOT	–	United States Department of Transportation
EPA	–	United States Environmental Protection Agency
EPCRA	–	Emergency Planning and Community Right-to-Know Act
HAL	–	Health Advisory Limit
LEPC	–	Local Emergency Planning Committee
NAICS	–	North American Industry Classification System
NPL	–	National Priorities List
NRC	–	National Response Center
OIRA	–	Office of Information and Regulatory Affairs
OMB	–	United States Office of Management and Budget
PFAS	–	Per- and Polyfluoroalkyl Substances
PFOA	–	Perfluorooctanoic Acid
PFOS	–	Perfluorooctanesulfonic Acid
RCRA	–	Resource Conservation and Recovery Act
RFA	–	Regulatory Flexibility Act
RQ	–	Reportable Quantity
SBA	–	United States Small Business Administration
SBREFA	–	Small Business Regulatory Enforcement Fairness Act of 1996
SERC	–	State Emergency Response Commission
SISNOSE	–	Significant Impact on a Substantial Number of Small Entities
TEPC	–	Tribal Emergency Planning Committee
TERC	–	Tribal Emergency Response Commission
UMRA	–	Unfunded Mandates Reform Act
WWTPs	–	Wastewater Treatment Plants

TABLE OF CONTENTS

EXECUTIVE SUMMARY

ES-1 Introduction

Background

Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) are synthetic chemicals that are resistant to heat, water, and oil. For decades, they have been used in hundreds of industrial applications and consumer products such as carpeting, apparel, upholstery, food paper wrapping, firefighting foam, and metal plating. In recent years the use of PFOA and PFOS in producing these materials has greatly declined. Although some uses of PFOS are still ongoing (see 40 CFR §721.9582), the usage of PFOA and PFOS in the United States is relatively low. Nonetheless, the chemical makeup and effects of PFOA and PFOS warrant action. PFOA and PFOS are part of a large group of human-made, fluorinated, organic chemicals called Per- and Polyfluoroalkyl Substances (PFAS).

Need for Regulatory Action

Designating PFOA and PFOS as CERCLA hazardous substances furthers CERCLA's primary goal of protecting public health and welfare and the environment through a variety of means. It improves the quality of information available and will result in a more comprehensive understanding of the number and locations of PFOA and PFOS releases meeting or exceeding the reportable quantity (RQ). It will also signal to the market that there is value in the prevention of releases. An indirect effect of the designation is the improved ability to transfer response costs from the public to polluters, and the potential to accelerate privately financed cleanups. Based on data compiled from the Superfund Enterprise Management System (SEMS), EPA funded the remedial actions at 29 percent of ongoing NPL sites in 2019, compared to 47 percent funded by potentially responsible parties (PRPs), and 9 percent with mixed financing. Data on the financing for the remaining 15 percent was not reported in SEMS.[1,2] Categories of response costs that may potentially be transferred include costs related to (but not limited to) laboratory testing, remedy design, construction and operation of groundwater treatment systems, disposal of hazardous substances removed from the site, and groundwater monitoring following completion of clean-up.

Summary of Proposed Rule

[1] Katherine N. Probst, "Superfund at 40: Unfulfilled Expectations," in Hampden T. Macbeth (ed.), *Looking Back to Move Forward: Resolving Health & Environmental Crises*, State Energy & Environmental Impact Center, NYU School of Law, November 2020.

[2] Information on the amount spent on clean-ups by PRPs relative to EPA are not available, as PRPs are not required to report their actual expenditures to EPA.

Under Section 102(a) of CERCLA, the EPA is proposing to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances. The proposal to designate PFOA and PFOS including their structural isomers and salts, as hazardous substances results in the following CERCLA requirements:

- Report to the National Response Center (NRC) when releases occur in amounts equal to or greater than their reportable quantity of one pound or more in a 24-hour period, as required under CERCLA section 103; and
- For such releases, notify the State Emergency Response Commissions (SERC) (or Tribal Emergency Response Commission (TERC)) and Local Emergency Planning Committee (LEPC) (or Tribal Emergency Planning Committee (TEPC)) of the release and prepare and submit a written follow-up notice, as required for CERCLA hazardous substances under EPCRA section 304; and
- When federal agencies sell or transfer federally-owned property, CERCLA section 120(h) requires that they must provide notice when "any hazardous substance was stored for one year or more, known to have been released, or disposed of", and provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any such substance remaining on the property has been taken before the date of such transfer, and any additional remediation action found to be necessary after the date of such transfer shall be conducted by the United States." And
- Substances designated as hazardous under CERCLA are required to be listed by DOT in the Hazardous Materials Regulations (49 CFR parts 171-180) under the Hazardous Materials Transportation Act. (See Section 306(a) of CERCLA.).

ES-2 Entities that have Historically used PFOA and PFOS

Types of Entities Potentially Affected by the Proposed Regulations

PFOA and PFOS were two of the most extensively produced PFAS in the United States but were largely phased out of domestic production voluntarily after 2002.[3] However, the chemicals are still produced internationally and can be imported into the United States for industrial uses or in articles and consumer goods such as leather, apparel, textiles, paper and packaging, coatings, rubber, and plastics.

[3] Fact Sheet: 2010/2015 PFOA Stewardship Program: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program.

Building on the 2002 voluntary phase out, EPA has used the following mechanisms to restrict current uses of PFOS and PFOA:

- PFAS Significant New Use Rule (SNUR) – March/December 2002
- The PFOA Stewardship Program - 2010/2015
- PFAS Significant New Use Rule (SNUR) - 2013
- PFAS Significant New Use Rule (SNUR) – 2020

Under these regulatory and non-regulatory mechanisms, current PFOS uses are limited to anti-erosion additives in fire-resistant aviation hydraulic fluid; fume/mist suppression in metal finishing and plating; etching and plating uses, including mist suppression, in electronics manufacturing; a photomicrolithography process in semiconductor production; coatings on imaging materials; and as a chemical intermediate to produce substances for some of the aforementioned uses.[4] Fewer definite limitations are in place regarding PFOA uses. Therefore, although PFOA use has also been understood to decline significantly over the last two decades, the current usage and PFOA's specific uses are uncertain.

The three categories of entities potentially affected by the proposed regulation are: (1) producers and importers of PFOA and PFOS, (2) producers and users of PFOA- or PFOS-containing articles, and (3) waste management and treatment facilities. Across these three categories, there are at least 35 different sectors with known or suspected historical PFOA or PFOS production or use.

Manufacture and import of both PFOS and PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program.[5] PFOA may be manufactured, imported, and used by companies not participating in the PFOA Stewardship Program and some uses of PFOS are ongoing (see 40 CFR §721.9582).[6] Many sectors are potential users of manufactured products that contain PFOA or PFOS. PFOA or PFOS have historically been a component of firefighting foams, surfactants, etching agents, stain- and water-resistant applications, car waxes, architectural coatings, and antistatic control.

Wastewater treatment plants (WWTPs) may receive wastewater that contains PFOA or PFOS from a variety of sources, including industries that manufacture or use PFOA and PFOS, and PFOA- and PFOS- containing consumer and industrial products. PFOA and PFOS are the most

---

[4] https://www.ecfr.gov/cgi-bin/text-idx?SID=c8175aed22d0b9446beca21293ba915f&mc=true&node=se40.33.721_19582&rgn=div8.
[5] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas#pfoa.
[6] ATSDR. 2021. Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237

widely detected PFAS compounds in wastewater and treatment units at conventional WWTPs. At present, WWTPs do not remove these compounds effectively.[7] As a result, effluent discharged to receiving water bodies and WWTP sludge may contain PFOA and PFOS. WWTPs may dispose of sludge by incineration, which can destroy PFOA and PFOS, or WWTPs may send sludge to a landfill. Sludge also is commonly applied to land as a fertilizer or soil amendment.

Baseline Regulations affecting PFOA and PFOS and Associated Facilities and Systems

Although PFOA and PFOS are not currently designated as CERCLA hazardous substances, EPA has used existing authority to address PFAS (including PFOA and PFOS) releases under the Safe Drinking Water Act (SDWA), TSCA, RCRA, and CERCLA.[8] The Agency has used CERCLA authority to gather existing information (e.g., sampling data and information on management and disposal practices) on PFAS (including PFOA and PFOS) at certain sites and facilities. Additionally, under federal facility agreements, which apply to pollutants and contaminants, federal agencies are required to address PFOA and PFOS releases at federal facility NPL sites. Beyond federal actions taken to address PFOA and PFOS, state governments continue to develop regulatory structures and analytic approaches to identify, characterize, and address PFOA and PFOS exposure. In all, at least 29 states either have or currently are setting standards, screening levels, and guidance values for PFOA and PFOS (and sometimes other PFAS compounds). EPA found little to no documentation of PFAS on the websites of the remaining state environmental departments and departments of health. Based on EPA's review, these state standards would not offset any of the direct costs and benefits expected from this proposed rulemaking as states are not currently requiring entities to report releases to federal entities.[9]

ES-3 Costs, Benefits, and Transfers

Quantified Direct Costs

The explicit reporting requirements associated with designation of PFOA and PFOS as hazardous substances include the requirement under CERCLA section 103(a) to notify the National Response Center (NRC) of a release above the RQ and the requirements under EPCRA section 304 to notify State Emergency Response Commissions (SERC) (or TERC) and Local Emergency Planning Committees (LEPC) (or TEPC) of a release and to prepare and submit a written follow-up notice. Based on data in two Information Collection Request documents

---

[7] Schultz, Melissa M., Christopher P. Higgins, Carin A. Huset, Richard G. Luthy, Douglas F. Barofsky, and Jennifer A. Field. Environmental science & technology. 2006. "Fluorochemical mass flows in a municipal wastewater treatment facility.", 7350-7357.
[8] To date, EPA has addressed PFAS in 16 cases using enforcement tools under these regulations.
[9] Toxics Use Reduction Institute, "Per- and Poly-fluoroalkyl Substances (PFAS): Policy Analysis," May 2021. Available: https://www.mass.gov/doc/turi-pfas-policy-analysis-may-2021/download

published by EPA, the total reporting cost for a facility submitting both telephone notifications and a written notification is estimated to be approximately $561.[10,11] Incremental detection and measurement costs are assumed to be zero or negligible, as affected facilities are likely to incur such costs in the baseline to comply with reporting requirements related to the Toxics Release Inventory (TRI). EPA assumes there will be no incremental costs to train staff on the assessment of spilled PFOA/PFOS quantities. If an entity is handling these chemicals and there is a PFOA/PFOS release at its site, we assume that it has the capability to assess spilled quantities and that its staff are sufficiently trained for this purpose. In addition, EPA assumes that incremental costs associated with rule familiarization will be de minimis. Facilities should already be familiar with baseline requirements associated with reporting releases of non-PFOA/PFOS hazardous substances to the NRC and to other state and local emergency entities as required under EPCRA. While this rule increases by two the number of substances whose release above the RQ triggers reporting to the NRC and other state and local emergency agencies, the rule does not require changes to existing requirements or procedures already in existence. EPA requests comment on expected rule familiarization costs per affected entity.

The precise number of reportable releases of PFOA and PFOS is not known. EPA requests comment on the number of PFOA and PFOS releases expected going forward. In FY 2020 the NRC received approximately 23,807 total notifications of releases of all types of hazardous substances. Of all non-oil releases reported, hazardous substances containing multiple forms of ammonia or ammonium compounds accounted for the largest number of releases in 2020, 660 in total.

To estimate an upper bound of annual PFOA and PFOS release notifications, EPA adopts the number of reported releases of ammonia or ammonium compounds (i.e., the compounds with the highest number of reported releases) in 2020. To estimate a lower bound of annual PFOA and

---

[10] See EPA, Information Collection Request (ICR) No. 1049.14: Renewal of Information Collection Request for the Episodic Releases of Oil and Hazardous Substances. OMB Control No. 2050-0046, June 2018; and EPA, Information Collection Request (ICR) No. 1395.10: Statement Supporting the Renewal of the Information Collection Procedure for Emergency Planning and Release Notification Requirements. OMB Control No. 2050-0092. April 2019.

[11] In 1985, EPA published an RIA examining reportable quantity adjustments under Sections 102 and 103 of CERCLA. This RIA presented unit costs for reporting and recordkeeping to regulated parties as well as notification processing to the government. In 2020$, reporting costs to regulated parties published in the 1985 RIA were between $269.06 and $718.24 depending on the quantity reported. Additionally, in 2020$, the 1985 RIA reported a unit cost of $62.48 for recordkeeping to responsible parties and $155.66 for notification processing to the government. The reporting costs per release under CERCLA and EPCRA requirements presented in Exhibit 3-1 are within the range of the estimates published in the 1985 RIA.
The full citation to EPA's 1985 RIA is here: ICF. 1985. Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act. Volume 1: A Report to the Oil and Hazardous Materials Spills Branch Office of Research and Development and Environmental Response Division, Office of Emergency and Remedial Response, U.S. EPA. EPA Contract 68-03-03182

PFOS release notifications, EPA adopts a value of zero. This Regulatory Impact Analysis (RIA) estimates total annual notification costs for this action by multiplying this wide range of estimated annual PFOA and PFOS notifications nationally by the estimated cost of notification per site. **Exhibit ES-1** summarizes the range of total annual notification costs. As the exhibit shows, total annual notification costs are an estimated $0 to $370,000. EPA requests comment on the assumption that ammonia or ammonium releases provide a reasonable upper bound for PFOA and PFOS releases.

Exhibit ES-1
Estimated Total Annual Notification Costs
(adjusted to 2020$)

Estimated Annual Number of Notification in United States	Estimated Notification Costs (Total)
0 - 660	$0 - $370,000

Potential direct costs may also result from the DOT requirement to list and regulate CERCLA designated hazardous substances as hazardous materials under the Hazardous Materials Transportation Act (see CERCLA Section 306(a)). As described in Section 3.4, we estimate these incremental costs as zero. Because production of PFOA and PFOS are understood to have been largely phased out of production and use beginning in 2000, it is unlikely that regulated entities would ship PFOA or PFOS in quantities equal to or above the RQ.

Unquantified Direct Costs

The proposed rule creates costs associated with CERCLA section 120(h) requirements for federal agencies to provide notice of the release of hazardous substances and covenants regarding the remediation, if necessary, of such hazardous substances when selling or transferring federally-owned real property to any other person or entity. The number and magnitude of future federal property sales and transfers involving property with PFOA and/or PFOS releases is highly uncertain, therefore this analysis does not attempt to quantify such costs.

Qualitative Discussion of Direct Benefits

Qualitative benefits of this action include improved quality of information and a more comprehensive understanding of the number and location of sites with future releases of PFOA and PFOS which meet or exceed the RQ. Specifically, the reporting requirement will make available information about potential contamination that may be valuable for evaluating decisions about mitigating and reducing risk. Other direct benefits could include attention to better waste management and/or treatment practices for facilities handling PFOA or PFOS in an effort to avoid releases of these substances into the environment. Incentivizing the prevention of releases is expected to decrease potential threats to public health and welfare and the environment.

Qualitative Discussion of Indirect Costs, Benefits, and Transfers

In addition to direct costs and benefits, the proposed rule may result in indirect costs and benefits associated with potential increases in the speed of response activity and the total number of response actions. Indirect benefits may include health benefits associated with near-term avoided risk and longer-term site response activities, and potentially improving litigation efficiency as a result of reducing public entities burden of proof requirements related to contamination. Indirect costs may result from the movement forward in time of assessment and cleanup costs.

An important outcome of the proposed rule is that with PFOA and PFOS designated as CERCLA hazardous substances, response costs are more likely to be borne by responsible parties. Cost transfers from the public to parties responsible for pollution are associated with the enhancement of EPA's existing authority under CERCLA 104(a) to recover costs incurred by the government for site-specific response actions. However, when the federal government is the responsible party for PFOA or PFOS pollution, the public continues to incur associated response costs although they are moved between federal budgets.

Summary of Uncertainties Regarding Indirect Costs, Benefits, and Transfers

This proposed rule has potential indirect impacts that are important, but that pose significant challenges to quantification. Key information that would enable quantification is unavailable. Critical data that are missing include, among others (1) the number and types of sites that might need response activities along with information on the magnitude and extent of PFOA and PFOS contamination; (2) the cleanup standards that must be met by remedial activities; and (3) the technologies, and their associated costs, for assessing and remediating the various contaminated media at sites. EPA lacks information on the number of existing NPL sites that might face incremental costs to address PFOA or PFOS contamination, and on the number of new sites that might be identified as needing assessment or other response activities. Federal cleanup standards continue to evolve and site remediation to date has been focused on sites of specific concern to various states and localities, with varying cleanup objectives. Associated costs may therefore reflect fluctuating levels of concern or types of sources. It is important to note that PFOA or PFOS detections or use at a site does not imply that response action is necessary. Response actions, which include investigations of hazardous substance releases and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific, as described in Chapter 3.

Technological options for assessing and responding to PFOA and PFOS contamination are evolving. Thus, empirical data on their costs are limited. For example, the incremental cost of addressing PFOA and/or PFOS relative to baseline costs of cleaning other contaminants on existing NPL sites is unknown. PFOA and PFOS present at a site with other hazardous substances may be addressed with treatment methods used for other hazardous substances, in which case addressing PFOA and PFOS risks would not result in additional response costs above the baseline. In addition, specific-site assessment and remediation activity may or may not be representative of potential future sites in need of assessment and cleanup, in scope or cost,

indirectly affected by the proposed rule. This lack of information prevents quantitative assessment of indirect response costs, benefits, and potential transfers.

ES-4 Statutory and Executive Order Analyses

Regulatory Flexibility Analysis

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR Part 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

To estimate the annual breakeven costs per facility (i.e., the facility-level cost that would indicate that the cost might be significant in this context), the analysis relies on three pieces of information for each industry: (1) average annual revenues per small entity[12], (2) average number of facilities per small entity, and (3) the target breakeven percentage of costs to revenues (either one percent or three percent).

Exhibit ES-2 estimated breakeven costs per small entity (firm) and per facility, by industry. These results are presented using six-digit NAICS codes.[13]

Although the number of small entities in any sector that would be required to report as a result of the action under consideration by EPA is uncertain, given the phase out of the use of PFOA and PFOS in the US, in general EPA would expect few if any small entities, including small government entities, to need to undertake a release report. Chapter 2 discusses the historical uses and subsequent efforts to phase out the use of PFOA and PFAS in the United States. EPA expects such reports to be on an as-needed basis and does not expect that reporting costs would be incurred on an annual basis. However, to be conservative, EPA compares the total per release cost of $561, to the average revenues for small entities in key sectors potentially affected by PFAS. The estimate of $561 does not come close to exceeding one percent of average small-entity revenues in any sector. In addition, the $561 per release cost represents an estimate of the

---

[12] Note that for each industry this value is calculated using average annual revenues among *small* entities in a particular industry, not the average among all entities in that industry. Estimates of notification costs obtained from EPA, Information Collection Request (ICR) No. 1049.14: Renewal of Information Collection Request for the Episodic Releases of Oil and Hazardous Substances. OMB Control No. 2050-0046, June 2018; and EPA, Information Collection Request (ICR) No. 1395.10: Statement Supporting the Renewal of the Information Collection Procedure for Emergency Planning and Release Notification Requirements. OMB Control No. 2050-0092. April 2019.

[13] The NPRM lists the following three-digit NAICS codes as containing potentially relevant entities: 324 - Petroleum Refining Industry, 325 - Chemical Manufacturing Sector, and 562 - Waste Management and Remediation Services; relevant six-digit NAICS codes withing these entities are captured in **Exhibit ES-2**.

average cost incurred by all entities in the affected universe from large industrial operations to car washes. It is likely an overestimate for small entities which tend to employ fewer staff and have less management overhead.

For the sector with the lowest breakeven costs per facility (Car Washes – NAICS 811192), the smallest size class reported has a revenue average of $48,496. Even in this class, the per release cost of $561 represents less than three percent of revenues and just slightly more than one percent of revenues.[14] Similarly, for five other industries,[15] the $561 cost per release is slightly more than one percent of revenues for the smallest revenue class among small entities but less than three percent (range of 1.02 percent to 1.08 percent). The annual revenues for these entities range from $51,980 to $55,256. Collectively, these entities represent less than 9 percent of the small entities reflected in Exhibit 4-1. In addition, the $561 cost is likely to overestimate the typical costs realized by these entities on an annual basis, as entities this small are unlikely to have reportable releases each year. EPA therefore expects that the impact on a substantial number of small entities would not be significant. However, the Agency requests comment on the annual number of releases expected per small entity, and any other information that could help EPA estimate small entity reporting costs.

[14] Data obtained from United States Census Bureau's 2017 Statistics of U.S. Businesses (SUSB). Values converted from year 2017 dollars to year 2020 dollars using the GDP Deflator.
[15] The five other industries are Other Airport Operations (NAICS 488119); Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS 332813); Surgical and Medical Instrument Manufacturing (NAICS 339112); Fabric Coating Mills (NAICS 313320); and Sewage Treatment Facilities (NAICS 221320).

Exhibit ES-2 Breakeven Estimates for Annual Costs per Facility (adjusted to 2020$)							
Industry	**NAICS Code and Description**	**Annual Revenues per Small Entity [a]**	**Average Number of Facilities per Small Entity [b]**	**Breakeven Annual Cost per Entity: 1% Threshold [c = (1% × a)]**	**Breakeven Annual Cost per Entity: 3% Threshold [d = (3% × a)]**	**Breakeven Annual Cost per Facility: 1% Threshold [e = (1% × a)/b]**	**Breakeven Annual Cost per Facility: 3% Threshold [f = (3% × a)/b]**
Aviation operations	488119 - Other Airport Operations	$2,537,912	1.11	$25,379	$76,137	$22,939	$68,818
Carpet manufacturers	314110 - Carpet and Rug Mills	$8,527,078	1.05	$85,271	$255,812	$81,335	$244,006
Car washes	811192 - Car Washes	$569,439	1.07	$5,694	$17,083	$5,313	$15,939
Chrome electroplating, anodizing, and etching	332813 - Electroplating, Plating, Polishing, Anodizing, and Coloring	$3,194,451	1.04	$31,945	$95,834	$30,704	$92,111
Coatings, paints, and varnish	325510 - Paint and Coating Manufacturing	$8,579,550	1.08	$85,796	$257,387	$79,697	$239,090
Firefighting foam manufacturers	325998 - All Other Miscellaneous Chemical Product and Preparation Manufacturing	$9,615,850	1.06	$96,159	$288,476	$91,107	$273,322
Landfills	562212 - Solid Waste Landfill	$2,732,229	1.02	$27,322	$81,967	$26,744	$80,231
Medical Devices	339112 - Surgical and Medical Instrument Manufacturing	$10,924,915	1.05	$109,249	$327,747	$104,317	$312,950
Municipal fire departments and firefighting training centers	922160 - Fire Protection	N/A	N/A	N/A	N/A	N/A	N/A
Paper mills	322121 - Paper (except Newsprint) Mills	$109,190,104	1.28	$1,091,901	$3,275,703	$851,896	$2,555,688
	322130 - Paperboard Mills	$53,571,512	1.08	$535,715	$1,607,145	$495,518	$1,486,553
Petroleum refineries and terminals	324110 - Petroleum Refineries	$919,097,728	1.16	$9,190,977	$27,572,932	$7,948,953	$23,846,860
	424710 - Petroleum Bulk Stations and Terminals	$54,054,028	1.21	$540,540	$1,621,621	$445,151	$1,335,452
Pesticides and Insecticides	325320 - Pesticide and Other Agricultural Chemical Manufacturing	$25,079,234	1.06	$250,792	$752,377	$236,296	$708,887
Photographic film manufacturing	325992 - Photographic Film, Paper, Plate, and Chemical Manufacturing	$3,410,199	1.05	$34,102	$102,306	$32,595	$97,784
Polishes, waxes,	325612 - Polish and Other	$9,060,815	1.04	$90,608	$271,824	$86,932	$260,796

Exhibit ES-2 Breakeven Estimates for Annual Costs per Facility (adjusted to 2020$)							
Industry	NAICS Code and Description	Annual Revenues per Small Entity [a]	Average Number of Facilities per Small Entity [b]	Breakeven Annual Cost per Entity: 1% Threshold [c = (1% × a)]	Breakeven Annual Cost per Entity: 3% Threshold [d = (3% × a)]	Breakeven Annual Cost per Facility: 1% Threshold [e = (1% × a)/b]	Breakeven Annual Cost per Facility: 3% Threshold [f = (3% × a)/b]
cleaning products	Sanitation Good Manufacturing						
Polymer manufacturing	325211 - Plastics Material and Resin Manufacturing	$33,570,756	1.14	$335,708	$1,007,123	$293,955	$881,864
Printing facilities where inks are used in photolithography	323111 - Commercial Printing (except Screen and Books)	$2,256,953	1.03	$22,570	$67,709	$21,930	$65,790
	325910 - Printing Ink Manufacturing	$7,404,767	1.35	$74,048	$222,143	$54,671	$164,012
Textile mills (textiles and upholstery)	313210 - Broadwoven Fabric Mills	$8,800,871	1.04	$88,009	$264,026	$84,396	$253,189
	313220 - Narrow Fabric Mills and Schiffli Machine Embroidery	$4,053,810	1.04	$40,538	$121,614	$39,164	$117,492
	313230 - Nonwoven Fabric Mills	$16,383,181	1.08	$163,832	$491,495	$151,160	$453,479
	313240 - Knit Fabric Mills	$8,001,426	1.01	$80,014	$240,043	$79,434	$238,303
	313320 - Fabric Coating Mills	$12,333,111	1.06	$123,331	$369,993	$116,573	$349,720
WWTPs	221320 - Sewage Treatment Facilities	$1,357,425	1.06	$13,574	$40,723	$12,786	$38,357

Note: Revenue values obtained from United States Census Bureau's 2017 Statistics of U.S. Businesses (SUSB). Values converted from year 2017 dollars to year 2020 dollars using the GDP Deflator.

Note: EPA did not consider the cost impacts on small government municipal drinking water utilities because they were not identified as potential major sources of PFOA and/or PFOS releases in any of the literature reviewed.

Impact on Minority and Low-Income Population

This RIA includes a screening-level analysis of the demographics of the populations in proximity to potential sites that have historically used PFOA and/or PFOS and considers the possible impact of the proposed rule on populations and locations relevant to Executive Orders 12898 and 14008.

This demographic analysis examines populations in U.S. Census block groups that intersect with identified site boundaries or centroids and designated areas around them (i.e., buffers). [16]

This proposed regulation identifies groundwater and surface water as potential sources of exposure for the identified PFAS. Because the location of future releases of PFAS is uncertain, this analysis considers populations around facilities in sectors associated with widespread historical uses and releases of PFAS as proxies for facilities that may have future releases of the PFAS considered in the proposed rule. This analysis examines the following site types as proxies for facilities that are known to have commonly used PFAS:

- Operating Department of Defense (DOD) facilities[17]
- Operating U.S. airports and airfields[18]
    - Large U.S. airports and airfields
    - All other U.S. airports and airfields (i.e., medium and small)
- Plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA[19,20]

---

[16] This demographic analysis iterates the screening level method employed by EPA's Office of Land and Emergency Management (OLEM) to characterize the populations around sites subject to regulation and remediation under the RCRA and CERCLA statutes (as well as programs related to brownfields and underground storage tanks). OLEM is planning to refine the population apportionment method in 2022 to better capture site-specific impacts; this is not likely to affect the results of national-level screening analyses such as the one in this RIA, but will be incorporated in the final rule.

[17] Operating DOD facilities include bases, depots, training sites, camps, forts, research facilities, military airfields, etc. Dataset was acquired from: U.S. Army Corps of Engineers, "DoD Sites", June 2021. Accessed at: https://catalog.data.gov/dataset/dod-sites-boundary & https://catalog.data.gov/dataset/dod-sites-point.

[18] Because the National Plan of Integrated Airport Systems (NPIAS) public facing dataset presented by the Federal Aviation Administration (FAA) does not contain geographic information, this analysis relies on data from the United Nations Office for the Coordination of Humanitarian Affairs to provide location information for facilities identified in the FAA dataset. To assess the coverage of the UN database, this analysis cross-referenced the list of airports represented in both datasets; this exercise found that the UN data contained 98% of all airports listed in the NPIAS. Of the 2% of sites listed in the NPIAS but not in the UN database, about half were located in rural Alaska. Full citations of these datasets are presented below:
(1) United Nations Office for the Coordination of Humanitarian Affairs, "The Humanitarian Data Exchange: Airports in the United States of America", June 2021. Downloaded on June 18, 2021. Accessed at: https://data.humdata.org/dataset/ourairports-usa. The dataset categorized airports by the following size categories: small, medium, and large.
(2) Federal Aviation Administration. "National Plan of Integrated Airport Systems (NPIAS) - Current – Airports", October 07, 2020. Downloaded February 2022. Accessed at: https://www.faa.gov/airports/planning_capacity/npias/current/

- 2020 PFOS and PFOA releases reported to EPA's Toxic Release Inventory (TRI)[21]

EPA requests comment on the PFAS release levels from these facilities and the types of PFAS that they release.

Exhibit ES-3 summarizes several key demographics of the total populations near the universe of proxy sites identified and compares these demographics to U.S. national averages. The six key demographic categories examined are minority (reflecting an examination of both race and ethnicity; minority is defined as populations excluding non-Hispanic White), poverty level, linguistic isolation, education, age (specifically population less than five years old and greater than 64 years old), and age of housing.

These findings, combined with the uncertainty surrounding the location of future releases, are indicative of potential impacts but do not provide a clear indication of the type of disparities related to potential exposure to PFAS. Consistent with the priorities outlined in Executive Orders 12898 and 14008, it is unclear whether the proposed regulation will have a significant impact on disadvantaged populations or communities with environmental justice (EJ) concerns relative to other communities. While the locations of reporting releases are unknown, to the extent that these proxy locations are representative of likely reporting locations, this screening analysis suggests that the reporting required under the rule may provide better information to nearby populations potentially at risk of exposure, including communities with environmental justice (EJ) concerns. To the extent that PFAS releases are consistent with the broader releases reported to TRI and typically involve disposal or manufacturing sites, demographic data around plastics material and resin manufacturer sites and historical releases may be a more reliable predictor of the type of community potentially affected by this proposed rulemaking. Specific site conditions and demographic patterns may become clear as reporting occurs following completion of a final rule.

---

[19] Data was acquired from: Environmental Protection Agency, "Enforcement and Compliance History Online (ECHO)", August 2021.

[20] Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this RIA drops all facilities that are not owned by the following companies: 3M, Dupont, Chemours, Arkema, Asahi, BASF, Clariant, Daikin, or Solvay Solexis. All companies, except Chemours, were listed by EPA as participants in the PFOA Stewardship Program. Chemours, a spin-off of Dupont, is a known manufacturer of PFAS products and is listed in a lawsuit filed by the State of Michigan. Sources: (1) Environmental Protection Agency, "Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA", 2021. Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas (2) Michigan Department of Environment, Great Lakes, and Energy, "Michigan Files Lawsuit Against 3M, DuPont and others for PFAS Contamination", 2020. Link: https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-517280--,00.html.

[21] Environmental Protection Agency, "Envirofacts: TRI Search", July 2021. Accessed at: https://www.epa.gov/enviro/tri-search.

Additional details on the application of the demographic data and the implications of the environmental justice analysis are presented in Chapter 4. As described in Chapter 4, the analysis of demographic data found that populations living within one or three miles of plastics material and resin manufacturers, PFOS or PFOA releases reported in the TRI, Department of Defense facilities, and large airports exhibited one or more indicators of social vulnerability (e.g., poverty rate exceeding the national average).

Exhibit ES-3
Proportions of Key Demographics in the Total Near Site Population and the Total U.S. Population

Demographic Category	Population within 1 or 3 miles of a Plastics Material and Resin Manufacturer and/or a Release Reported to TRI		Population within 1 or 3 miles of a DOD site		Population within 1 or 3 miles of a Large Airport		Population within 1 or 3 miles of all other Airport (i.e. Small and Medium)		U.S. Population
	1 mile	3 miles	1 mile	3 miles	1 mile	3 miles	1 mile	3 miles	
Race									
Asian	6.02%	6.82%	7.93%	7.42%	6.22%	8.16%	3.73%	4.34%	5.39%
Black/African American	22.58%	23.56%	15.83%	16.34%	14.51%	17.03%	9.04%	10.26%	12.65%
Hawaiian/Pacific Islander	0.06%	0.08%	1.07%	0.55%	0.36%	0.33%	0.19%	0.19%	0.18%
Native American	0.44%	0.36%	0.78%	0.75%	0.71%	0.74%	0.91%	0.84%	0.83%
Other	7.80%	7.76%	10.94%	10.73%	11.65%	12.90%	7.23%	7.65%	8.26%
Minority									
Minority	48.49%	48.91%	50.94%	50.63%	48.71%	56.70%	32.11%	34.71%	39.56%
Ethnicity									
Hispanic (any race)	17.31%	16.06%	21.77%	22.98%	24.38%	28.39%	16.13%	16.97%	18.65%
Poverty Level									
Households below the poverty level	18.76%	16.65%	13.80%	14.61%	13.56%	15.31%	12.17%	13.01%	13.70%
Households with a ratio of income to poverty level of two and below	39.95%	36.70%	34.37%	34.58%	62.68%	62.34%	30.73%	31.82%	32.34%
Other Demographics									
Linguistically isolated households	4.17%	4.44%	5.32%	6.34%	6.51%	9.16%	3.10%	3.61%	5.08%
Less than a High School Education	9.55%	8.97%	7.58%	8.59%	8.82%	10.76%	8.11%	8.13%	8.44%
Under 5 years of age	6.25%	6.26%	7.20%	6.78%	7.30%	6.82%	6.26%	6.26%	6.13%
Over 64 years of age	12.98%	13.73%	12.08%	13.21%	11.04%	12.55%	15.55%	15.23%	15.29%
Structures Built Pre-1960	53.59%	48.48%	25.71%	29.73%	28.13%	34.50%	21.64%	24.78%	28.01%
Total U.S. Population Captured in Proximity									
% of U.S. Population Captured in Proximity	0.15%	1.42%	2.55%	10.08%	0.12%	2.83%	2.57%	23.87%	100%

ES-5 List of EPA Requests for Comment

To improve the visibility of EPA's requests for comment, following is a summary of all EPA's requests for comment that appear throughout this EA. For each, the request is summarized and the section in which the request is made is identified.

- EPA requests comment on the number of PFOA and PFOS releases expected going forward. (See Section ES-3)
- EPA requests comment on the assumption that ammonia or ammonium releases provide a reasonable upper bound for PFOA and PFOS releases. (See Section ES-3)
- EPA requests comment on the annual number of releases expected per small entity, and any other information that could help EPA estimate small entity reporting costs. (See Section ES-4)
- EPA requests comment on the PFAS release levels from these facilities and the types of PFAS that they release. (See Section ES-4)
- EPA requests comment on information about PFOA and PFOS production and the use by the eight companies that participated in the PFOA Stewardship Program that may be useful in understanding the extent and magnitude of localized environmental levels of the chemicals. (See Section 2.1.1)
- EPA requests comment on expected rule familiarization costs per affected entity. (See Section ES-3 and Section 3.1)
- EPA requests comment on the number of properties that were previously transferred out of federal control with a deed that includes a covenant to provide remedial action. (See Section 3.4)
- EPA requests comment on uncertainties regarding the unquantifiability of indirect cost, benefit, and transfer impacts as described below. (See Section 3.5)
- EPA requests information and comment that may allow EPA to estimate incremental indirect costs associated with this rule. (See Section 3.5)
- EPA requests comment on the R&D expenditures that may be necessary to ensure effective removal of PFOA and PFOS. (See Section 3.6.1)
- EPA requests comment on any R&D-related benefits that may result from the Proposed Rule. (See Section 3.6.2)
- EPA seeks information and comment that will allow EPA to estimate incremental costs associated with this rule. (See Section 3.7)
- EPA requests comment on the associated impacts to small governments, including small municipal drinking water utilities from the rule. (See Section 4.2.2)

CHAPTER 1. INTRODUCTION

This document presents an analysis by the U.S. Environmental Protection Agency (EPA) Office of Land and Emergency Management of the potentially affected facilities, social costs, and statutory and executive order impacts of a proposal to designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) including their salts and structural isomers, as hazardous substances under CERCLA.

The proposed rule for designation as a hazardous substance, if finalized, would require reporting of releases above the RQ of PFOA, PFOS, and their salts and structural isomers. The designation of PFOA and PFOS as hazardous substances, if finalized, would result in a default reportable quantity of one pound pursuant to CERCLA section 102.[22] Section 103 of CERCLA and 40 CFR 302.6 require any person in charge of a vessel or facility with knowledge of a release of a hazardous substance equal to or greater than the reportable quantity within a 24-hour period to immediately notify the National Response Center (NRC). Section 304 of the Emergency Planning and Community Right-to-Know Act (EPCRA) also imposes reporting requirements (to state, tribal, and local officials) for releases of hazardous substances above the RQ. The costs estimated by this analysis for the proposed designation are limited to reporting.

Other direct costs associated with CERCLA 120(h) requirements for future federal property sales or transfers are qualitatively described in this analysis. Potential indirect costs and cost transfers associated with response actions are also qualitatively described. Reporting does not trigger an obligation to conduct a response action. Response actions are site-specific decisions made after the hazardous substance release or threatened release and are contingent upon a series of statutory requirements and separate discretionary actions. The costs of transitioning to materials not containing PFOA or PFOS are not included because EPA does not have data on such costs and because transitions to other materials have already occurred for many uses in the baseline, due to voluntary programs, EPA's PFOA Stewardship Program, and Significant New Use Rules under the Toxic Substances Control Act (TSCA) (see discussion in Chapter 2). [23]

---

[22] While airports may not currently store or use quantities of PFOA or PFOS equal to or above one pound pursuant to CERCLA section 102 (or quantities sufficient to trigger release notification requirements for mixtures under CERCLA Section 103), this analysis notes them as known sites with past use of PFOA and PFOS and a broad geographic distribution. It is not clear what, if any, reporting obligations may be required by airports as a result of this rule.

[23] PFAS may still be used in firefighting foams used to fight flammable liquid fires. However, it is unclear how widespread its use remains, as PFAS are not required to be reported on safety data sheets since they are not considered a hazardous substance. See Michigan PFAS Action Response Team, "Firefighting Foam and PFAS," https://www.michigan.gov/pfasresponse/investigations/firefighting-foam, 2022.

There are direct and indirect benefits of this proposed rule. Designation as a hazardous substance incentivizes the prevention of releases by creating direct costs associated with reporting releases. Incentivizing the prevention of releases is expected to decrease potential threats to public health and welfare and the environment. Requiring that releases of PFOA and PFOS be reported will improve the quality of information and inform a more comprehensive understanding of the number and location of PFOA and PFOS releases meeting or exceeding the reportable quantity, potentially reducing risks to public health, and conferring benefits as described in detail in Chapter 3. Additional benefits from potential indirect impacts of the proposed designation on response activities are described below.

1.1 Background

PFOA and PFOS are synthetic chemicals that are resistant to heat, water, and oil. For decades, they have been used in hundreds of industrial applications and consumer products, including the following:

- As an additive in AFFF extinguishing foams, however, these are being actively replaced by PFOS-free extinguishing foams.
- Plating processes, such as a wetting agent/fume suppressant.
- Grease-, oil-, and water-resistant products, e.g. non-stick cookware, processing aids, paper/paperboard food packaging, food processing equipment, etc.
- Processing aids in fluoropolymer production.
- Processing aids in textile coating applications.
- Insecticides.
- Certain types of adhesives.
- Cleaning products, such as carpet cleaners, auto washes and electronics.
- Coating products, paints, varnishes and inks.
- Surfactants for oil extraction and mining.
- Photo lithography, photographic coatings and hydraulic fluids for aviation.[24,25]

[24] Environmental Protection Agency. Certain perfluoroalkyl sulfonates. U.S. Environmental Protection Agency. Code of Federal Regulations. 2014. 40 CFR 721.9582. https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-sec721-9582.pdf

[25] Glüge, J; Scheringer, M; Cousins, IT; DeWitt, JC; Goldenman, G; Herzke, D; Lohmann, R; Ng, CA; Trier, X; Wang, Z. (2020). An overview of the uses of per-and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts 22: 2345-2373. https://www.ncbi.nlm.nih.gov/pubmed/33125022

- Explosives and pyrotechnics as binders and oxidizers.

In recent years the use of PFOA and PFOS in producing these materials has greatly declined, in part due to voluntary phase out by industry. Although some uses of PFOS are still ongoing (see 40 CFR §721.9582), the usage of PFOA and PFOS chemicals in the United States is relatively low. PFOA and PFOS may be present in imported products and articles (except PFOA in carpet).

Scientists are still learning about the human health effects of PFOA and PFOS exposure. Studies have shown[26] that exposure to these compounds may

- affect growth, learning, and behavior of infants and older children,
- lower a woman's chance of getting pregnant,
- interfere with the body's natural hormones,
- increase cholesterol levels,
- affect the immune system, and
- increase the risk of cancer.

PFOA and PFOS are part of a large group of human-made, fluorinated, organic chemicals called PFAS. For many decades, PFOA and PFOS have been released into the environment contaminating environmental media and wildlife. PFAS generally, and PFOA and PFOS specifically, are sometimes referred to as "forever" chemicals because their carbon-fluorine bonds are strong, causing PFOA and PFOS to be extremely resistant to degradation in the environment. In addition to direct release of these chemicals, PFOA and PFOS can also be formed by chemical or biological degradation from a large group of related PFAS (i.e., precursor compounds).

The Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 et seq. (CERCLA or the Act) establishes broad Federal authority to respond to releases or threats of releases of hazardous substances from vessels and facilities. There are two ways that a substance may be defined as a "hazardous substance" under CERCLA. The first is automatic where the substance is identified as hazardous or toxic pursuant to other specified environmental statutes (e.g., chemicals listed as air toxics by Congress or EPA under Section 112 of the Clean Air Act). The second is where the substance is designated as hazardous pursuant to CERCLA Section 102. The Administrator of the EPA is authorized under CERCLA section 102(a) to promulgate regulations designating as a hazardous substance any substance which, when

[26] U.S. Department of Health & Human Services, "Per- and Polyfluoroalkyl Substances (PFAS) and Your Health," January 10, 2018. Available: https://www.atsdr.cdc.gov/pfas/health-effects.html.

released into the environment, may present substantial danger to public health or welfare or the environment. Designation as a CERCLA hazardous substance indicates a level of concern about a given substance sufficient to require a report to the National Response Center (NRC) in the event of a release in an amount equal to or greater than the reportable quantity (RQ) for that substance. Section 102(b) of the Act establishes RQs for releases of hazardous substances at one pound, except those substances for which RQs were established pursuant to section 311(b)(4) of the Clean Water Act (CWA) or where the default RQ is superseded by a regulation under CERCLA Section 102(a).

1.2 Need for Regulatory Action

Designating PFOA and PFOS as CERCLA hazardous substances would further CERCLA's primary goal of protecting public health and welfare and the environment through a variety of means. The designations would improve the quality of information available and inform a more comprehensive understanding of the number and locations of PFOA and PFOS releases meeting or exceeding the reportable quantity (RQ). These designations would also signal to the market that there is value in the prevention of releases. Indirect effects of the designation include the potential ability to transfer costs associated with response actions from the public to polluters, and the potential to accelerate privately financed voluntary cleanups. As a reference point for the burden borne by EPA for remedial actions, data compiled from the Superfund Enterprise Management System (SEMS) indicates that EPA funded the remedial actions in 29 percent of active NPL sites in 2019, compared to 47 percent funded by potentially responsible parties (PRPs), and 9 percent with mixed financing. Data on the financing for the remaining 15 percent was not reported in SEMS.[27,28] Categories of response costs that may potentially be transferred include, but are not limited to, direct, indirect, payroll, contractor, travel, and laboratory costs. These costs may be related to items such as (but not limited to) remedy design, construction and operation of groundwater treatment systems, disposal of hazardous substances removed from the site, and groundwater monitoring following completion of clean-up.

Additionally, a PFOA and PFOS hazardous substance designation would be consistent with and supportive of many actions by EPA, other federal agencies, states, tribes and various international bodies. Federal, state, and international governmental entities have already taken a wide variety of actions to address PFOA and PFOS contamination. For example:

[27] Katherine N. Probst, "Superfund at 40: Unfulfilled Expectations," in Hampden T. Macbeth (ed.), *Looking Back to Move Forward: Resolving Health & Environmental Crises*, State Energy & Environmental Impact Center, NYU School of Law, November 2020.

[28] Information on the amount spent on clean-ups by PRPs relative to EPA are not available, as PRPs are not required to report their actual expenditures to EPA.

- The DOD has been providing alternative drinking water to local residents near military bases with elevated levels of PFOA and PFOS in their drinking water from DoD activities.
- California, Michigan, and Vermont have drinking water standards for PFOA and PFOS.
- The European Union, and individual countries, such as Australia, China, and Canada, have also taken measures to address PFOA and PFOS.[29]

1.3 Summary of the Proposed Rule

Under Section 102(a) of CERCLA, the EPA is proposing to designate PFOA and PFOS, including their salts and structural isomers, as hazardous substances. The proposal to designate PFOA and PFOS including their structural isomers and salts, as hazardous substances results in the following CERCLA requirements:

- Report to the National Response Center (NRC) when releases occur in amounts equal to or greater than their reportable quantity of one pound or more in a 24-hour period, as required under CERCLA section 103; and
- For such releases, notify the State Emergency Response Commissions (SERC) (or Tribal Emergency Response Commission (TERC)) and Local Emergency Planning Committee (LEPC) (or Tribal Emergency Planning Committee (TEPC)) of the release and prepare and submit a written follow-up notice, as required for CERCLA hazardous substances under EPCRA section 304; and
- When federal agencies sell or transfer federally-owned, real property, they must provide notice of the presence of hazardous substances and covenants regarding the remediation of such hazardous substances in certain circumstances as required by CERCLA section 120(h).
- An obligation on DOT to list and regulate CERCLA designated hazardous substances as hazardous materials under the Hazardous Materials Transportation Act (see CERCLA Section 306(a)).

EPCRA and CERCLA are separate, but interrelated, environmental laws that work together to provide emergency release notifications to federal, state, tribal, and local officials. Under CERCLA, notices given to the NRC inform the federal government of a release, allowing federal personnel to evaluate the need for a response in accordance with the National Oil and Hazardous

[29] Environmental Protection Agency. Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances. U.S. Environmental Protection Agency, Proposed Rule. 2022. Docket ID No. EPA-HQ-OLEM-2019-0341. https://www.regulations.gov

Substances Contingency Plan. Under EPCRA, notices given to TERC, LEPC, and TEPC inform state, tribal, and local authorities about a release, allowing them to respond to protect the community and environment.

1.4 Scope of Analysis

This analysis examines quantifiable and qualitative direct and indirect costs, benefits, and other impacts for this proposed rulemaking and estimation of compliance costs associated with the rulemaking. Primarily, this analysis estimates costs associated with reporting releases of hazardous substances. It also considers costs resulting from federal property sales and transfers requirements associated with the alignment of CERCLA designation with other federal regulations. This rule directly targets information collection and reporting, this RIA only qualitatively examines the benefits associated with improved quality of information including better understanding of potential release events and sites.

The information about PFOA and PFOS hazardous substance releases that is collected as a result of this proposed action could inform separate decisions about responses to and remediation of releases. These subsequent actions, if any, are contingent on future site-specific decisions, and require separate actions by different Federal, State, Tribal, or local agencies in different jurisdictions with different regulatory structures. The Agency has concluded that the following barriers prevent developing a quantitative analysis of costs, benefits, and transfers associated with potential response actions: lack of adequate data availability about the extent of existing PFOA and PFOS use and contamination, evolving assessment technology and health science, and developing treatment and disposal technologies. A qualitative review of indirect cost, benefit, and potential cost transfer impacts is also included in Chapter 3.

In Chapter 4, this RIA also considers impacts of the rule related to certain Executive Orders and statutes, including but not limited to, the Unfunded Mandates Reform Act, impacts on Tribal Governments, and Federalism impacts.

1.5 Report Organization

EPA designed and conducted this analysis to be consistent with the requirements of Executive Order 12866, and OMB Circular A-4. Data, methods, and results of this analysis are presented in the following chapters:

- ***Chapter 2: Entities That Have Historically Used PFOA and PFOS.*** This chapter provides profiles of the entities that may be affected by the proposed rulemaking and the extent to which state regulations may already require compliance with the proposed regulations.

- ***Chapter 3: Assessment of Costs, Benefits, and Transfers.*** This chapter presents the estimated annual direct costs of compliance associated with the proposed rulemaking and describes the methodology used to develop these cost estimates. A qualitative description of direct benefits, as well as indirect costs, benefits, and potential transfers, is also included.

- ***Chapter 4: Statutory and Executive Order Analyses.*** This chapter summarizes analyses required by certain statutes or Executive Orders, including impacts related to energy systems, regulatory flexibility, minority and low-income populations, children's health, regulatory planning and review, unfunded mandates, federalism, and tribal governments.

CHAPTER 2. ENTITIES THAT HAVE HISTORICALLY USED PFOA AND PFOS

PFOA and PFOS were two of the most extensively produced PFAS in the United States but were largely phased out voluntarily after 2002.[30] However, the chemicals are still produced internationally and can be imported into the United States for industrial uses or in articles and consumer goods such as leather, apparel, textiles, paper and packaging, coatings, rubber, and plastics.

Building on the 2002 voluntary phase out, EPA has used the following mechanisms to restrict current uses of PFOS and PFOA:

- PFAS Significant New Use Rule (SNUR) – March/December 2002
- The PFOA Stewardship Program – 2010/2015
- PFAS Significant New Use Rule (SNUR) - 2013
- PFAS Significant New Use Rule (SNUR) – 2020

In March of 2002, a SNUR was published by EPA and focused on 13 chemicals involved in the voluntary phase out of PFOS by 3M that took place between 2000 and 2002. As such, new manufacturing or importing of PFOS and its derivatives became subject to EPA reporting and review unless it was characterized as a highly technical and limited use.[31] In December of 2002, another SNUR was published by EPA which built upon the March 2002 SNUR. Under this new SNUR, new manufacturing or importing of 75 PFAS chemicals specifically included in the voluntary phase out of PFOS by 3M became subjected to EPA review. Exemptions remained for PFOS manufacturing or importing that was deemed as highly technical or limited. [32,33]

In 2005, EPA invited eight companies within the PFAS industry to join a stewardship program aimed at achieving two goals[34]:

1) By 2010, achieve a 95 percent reduction in PFOA, including precursor chemicals that can break down to PFOA, from the baseline levels produced in 2000.

2) By 2015, eliminate these same chemicals from all emissions and products.

---

[30] Environmental Protection Agency. Fact Sheet: 2010/2015 PFOA Stewardship Program. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program
[31] https://www.govinfo.gov/content/pkg/FR-2002-03-11/pdf/02-5746.pdf.
[32] https://www.govinfo.gov/content/pkg/FR-2002-12-09/pdf/02-31011.pdf.
[33] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas.
[34] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas#pfoa.

The following eight companies participated in the program:

- Arkema
- Asahi
- BASF Corporation (successor to Ciba)
- Clariant
- Daikin
- 3M/Dyneon
- DuPont
- Solvay Solexis

As of 2015, all eight companies met the goals proposed by the stewardship program.

In 2013, EPA issued a SNUR[35] primarily designating PFAS chemical substances that have completed TSCA new chemical review process, but not yet commenced production or import as significant new use. Additionally, this SNUR required persons subject to the rule to notify EPA prior to commencing the import or use of PFOA for treating carpets.[36] In 2020, EPA issued a final rule strengthening the regulation of PFAS (i.e., PFOA and its salts, long-chain perfluoroalkyl carboxylate chemical substances) by requiring notice and EPA review before new use of long-chain PFAS. Additionally, products containing certain long-chain PFAS as a surface coating and carpet containing perfluoroalkyl sulfonate chemical substances can no longer be imported into the United States without EPA review.

Under this array of regulatory and non-regulatory mechanisms, current PFOS uses are limited to anti-erosion additives in fire-resistant aviation hydraulic fluid; fume/mist suppression in metal finishing and plating; etching and plating uses, including mist suppression, in electronics manufacturing; a photomicrolithography process in semiconductor production; coatings on imaging materials; and as a chemical intermediate to produce substances for some of the aforementioned uses.[37] Fewer definite limitations are in place regarding PFOA uses. Therefore, although PFOA has also been understood to decline significantly over the last two decades, PFOA's current usage and its array of specific applications are uncertain.

Although some limitations on production and use of PFOA and PFOS have been put into place, it is important to note that environmental contamination and human exposure to these chemicals are anticipated to continue for the foreseeable future due to their environmental persistence,

[35] https://www.federalregister.gov/documents/2013/10/22/2013-24651/perfluoroalkyl-sulfonates-and-long-chain-perfluoroalkyl-carboxylate-chemical-substances-final.

[36] Subsequent to the 2013 issuance, carpet uses do not appear to be occurring.

[37] https://www.ecfr.gov/cgi-bin/text-idx?SID=c8175aed22d0b9446beca21293ba915f&mc=true&node=se40.33.721_19582&rgn=div8.

formation from precursor compounds, continued production primarily by international manufacturers, and their long history of production in the United States.

This chapter provides a description of the entities that may be affected by the proposed regulation and documents the extent to which state regulations may already require compliance with the proposed regulation.

2.1 Types of Entities Potentially Affected by the Proposed Regulations

The current uses of PFOS have been greatly reduced following the finalization of the various SNURs. As noted, the use and usage of PFOA has also been understood to decline significantly over the last two decades, but its current usage and array of specific uses are uncertain.[38]

Generally, the three categories of entities potentially affected by the proposed regulation are: (1) importers and manufacturers of PFOA and PFOS, (2) users of PFOA- or PFOS-containing articles, and (3) waste management facilities. Across these three categories, there are at least 35 different sectors with known or suspected PFOA or PFOS production, use, or waste management.

2.1.1 Importers and Manufacturers of PFOA and PFOS

Manufacture and import of both PFOS and PFOA has been phased out in the United States by the eight global companies participating in the 2010/2015 PFOA Stewardship Program. In 2015, these companies eliminated the production and content of PFOA and related chemicals in their products.[39] A summary of the PFOA Stewardship Program including the goals, the participating companies, and related public documents is publicly available.[40] Although PFOA and PFOS are not produced domestically or imported by the companies participating in the 2010/2015 PFOA Stewardship Program, it is possible PFOA and PFOS may still be produced domestically or imported in very small quantities by other companies, i.e., those that did not participate in the PFOA Stewardship Program.[41] EPA requests comment on information about PFOA and PFOS production and the use by the eight companies that participated in the PFOA Stewardship Program that may useful in understanding the extent and magnitude of localized environmental levels of the chemicals. Additionally, EPA has regulated PFOA and other long chain PFAS by

[38] Interstate Technology and Regulatory Council, "History and Use of Per- and Polyfluoroalkyl Substances (PFAS)". April 2020. Available at: https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_History_and_Use_April2020.pdf.
[39] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas#pfoa.
[40] See the program summary here: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas#pfoa.
[41] ATSDR. 2021. Toxicological profile for perfluoroalkyls: final. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry. https://wwwn.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=1117&tid=237

requiring notice and EPA review before any phased-out use of long-chain PFAS could resume (see 40 CFR §721.9582). The Chemical Data Reporting rule requires manufacturers (including importers) to report PFOA and PFOS quantities if they meet or exceed 2,500 lbs at a single site. The last times PFOA and PFOS manufacture were reported to EPA as part of this collection effort were in 2013 and 2002, respectively. However, the 2020 Toxic Release Inventory (TRI) data shows that a small amount of PFOA and PFOS continue to be released into the environment.

2.1.2 Users of PFOA and PFOS

As explained in this chapter, PFOA and PFOS are no longer widely produced by U.S. manufacturers. Because many of these manufacturers also historically manufactured products containing PFOA and PFOS (i.e., firefighting foam, etching agents, car wax, etc.), this analysis assumes that the production of materials containing PFOA and PFOS has largely, but not necessarily completely, been eliminated from domestic manufacturing.

Although domestic manufacturing of materials containing PFOA and PFOS has largely ceased, many sectors are potential users of manufactured products that contain PFOA or PFOS. PFOA or PFOS have historically been a component of firefighting foams, surfactants, etching agents, stain- and water-resistant applications, car waxes, architectural coatings, and antistatic control. **Exhibit 2-1** below summarizes the users and associated products that, based on historical use, may contain PFOA and PFOS.

Exhibit 2-1
Summary of Users and Associated Products Historically Containing PFOA and PFOS

User	Products with PFOA and PFOS
Fire departments and firefighting training areas	Firefighting foam
Airports	Firefighting foam
Military installations	Firefighting foam
Petroleum refineries and terminals	Firefighting foam
Oil and mining production facilities	Surfactants
Chromium, copper, nickel, and tin electroplaters	Surfactants (to suppress chemical fumes and mist)
Pesticides and Insecticides	Surfactants and active substances
Medical Devices	Dispersant and stain- and water-resistant applications
Electronics and semiconductor industries etching	Etching agents
Paper mills	Paper for food contact applications and non-contact applications
Textile mills	Stain- and water-resistant applications
Furniture manufacturers	Stain- and water-resistant applications
Carwashes, car dealerships, and autobody shops	Car wax
Construction companies	Architectural coatings
Photographic film development	Antistatic control, surface tension control, friction control, and dirt repellency (particularly for faster speed films and sensitive diagnostic x-ray products)

2.1.3 Waste Management Facilities

Wastewater treatment plants (WWTPs) may receive wastewater that contains PFOA or PFOS from a variety of sources, including industries that manufacture or use PFOA and PFOS and PFOA- and PFOS-containing products. Examples include carwashes, runoff from firefighting training areas or oil fires, and households that use products containing PFOA and PFOS. Some companies may operate onsite wastewater treatment facilities, but typically they are not designed to remove PFOA and PFOS and their related compounds.

PFOA and PFOS are the most widely detected PFAS compounds in wastewater, and treatment units at conventional WWTPs. At present, WWTPs do not remove these compounds effectively.[42] As a result, effluent discharged to receiving water bodies and WWTP sludge may contain PFOA and PFOS. WWTPs may dispose of sludge by incineration, which can destroy PFOA and PFOS, or WWTPs may send sludge to a landfill.[43] While studies have shown nearly complete decomposition of certain PFAS at temperatures representative of heat levels at sewage sludge incinerators (SSIs), research on the emissions of PFAS compounds and thermal by-products (e.g., products of incomplete combustion) from full-scale SSIs has not been published to date.[44] Sludge also is commonly applied to land as a fertilizer or soil amendment. The use of biosolids on farmland can lead to the uptake of PFOA and PFOS in the food chain.[45] Industrial and municipal landfills also are receptors of PFOA- and PFOS-containing materials. In addition to biosolids from WWTPs, landfills may receive manufacturing wastes and household wastes (including food wrappings; empty cans of polish, wax, and cleaners; dental floss, etc.) that contain PFOA and PFOS, or chemicals that degrade to PFOA and PFOS. The leachate from municipal landfills is typically collected and sent to WWTPs for treatment, which can continue the introduction of PFOA and PFOS to the environment.

2.2 Baseline Regulations affecting PFOA and PFOS and associated Facilities and Systems

Although PFOA and PFOS are not currently designated as CERCLA hazardous substances, EPA has used existing authority and continues to address PFAS releases under the Safe Drinking

---

[42] Schultz, Melissa M., Christopher P. Higgins, Carin A. Huset, Richard G. Luthy, Douglas F. Barofsky, and Jennifer A. Field. Environmental science & technology. 2006. "Fluorochemical mass flows in a municipal wastewater treatment facility.", 7350-7357.

[43] Environmental Protection Agency. "Per- and Polyfluoroalkyl Substances (PFAS): Incineration to Manage PFAS Waste Streams", July 2019. Available at: https://www.epa.gov/sites/default/files/2019-09/documents/technical_brief_pfas_incineration_ioaa_approved_final_july_2019.pdf

[44] Winchell, Lloyd J.; John J. Ross; Martha J.M. Wells; Xavier Fonoll; John W. Norton, Jr; and Katherine Y. Bell. "Per- and polyfluoroalkyl substances thermal destruction at water resource recovery facilities: A state of the science review", June 2021. Water Environ Res, Vol. 93(6): 826-843.

[45] Susan Genualdi, Lowri deJager, and Timothy Begley. Center for Food Safety and Applied Nutrition, Food and Drug Administration. 2019. "Investigation of Per- and Polyfluoroalkyl Substances (PFAS) in U.S. food products", Presentation at the 29th annual European meeting of the Society of Environmental Toxicology and Chemistry.

Water Act (SDWA), TSCA, RCRA, and CERCLA.[46] The Agency has used CERCLA authority to gather existing information on PFAS at certain sites and facilities (e.g., sampling data and information on management and disposal practices). CERCLA section 104 authority has been used by EPA and other federal agencies to respond to PFAS releases. Additionally, under federal facility agreements, which apply to pollutants and contaminants, federal agencies are required to address PFOA and PFOS releases at federal facility NPL sites.

Beyond EPA's baseline regulations and other federal actions taken to address PFOA and PFOS, state governments continue to develop regulatory structures and analytic approaches to identify, characterize, and address PFOA and PFOS exposure. For example, New Hampshire has undertaken sampling for PFAS at drinking water supplies, wastewater treatment plants, fire stations, landfills, and contaminated waste sites to better understand the scope of contamination in the state. California also is planning a phased sampling effort targeting airports, landfills, refineries, bulk terminals, fire training areas, manufacturers that use PFAS in products or processes, and nearby water supply wells.[47]

Currently, a number of states have established regulatory structures and programs to address PFAS contamination.[48] For example:

- **Vermont** regulates PFOA and PFOS as hazardous wastes when present in a liquid at a concentration greater than 20 parts per thousand, but allows certain exemptions, including for sludge from wastewater treatment facilities or leachate from landfills when managed under an approved plan.

- **New York** finalized regulations in 2017 that specify storage and registration requirements for Class B firefighting foams containing at least one percent by volume of one or more of four PFAS (including PFOA and PFOS). The regulations prohibit the release of one pound or more of each into the environment during use. If a release exceeds the one-pound threshold, it is considered a hazardous waste spill and must be reported, and cleanup may be required under the state's Superfund or Brownfields programs.[49]

---

[46] To date, EPA has addressed PFAS in 16 cases using enforcement tools under these regulations.
[47] California Water Boards, "Water Boards PFAS Phased Investigation Approach," March 6, 2019. Available: https://www.waterboards.ca.gov/pfas/docs/7_investigation_plan.pdf.
[48] Interstate Technology and Regulatory Council, "Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS)," January 2018. Available: https://pfas-1.itrcweb.org/wp-content/uploads/2018/01/pfas_fact_sheet_regulations__1_4_18.pdf.
[49] In 2017, the New York Department of Environmental Conservation conducted a PFOS/PFOA Facility Identification Survey that revealed that six facilities had disposed of or released PFOS and/or PFOA onsite. Note, this survey may not predict the incidence of future releases after the implementation of the regulation in 2017. The survey is available here: New York Department of Environmental Conservation, "PFOS/PFOA Facility Identification Survey", 2017. Link: https://www.dec.ny.gov/docs/remediation_hudson_pdf/pfoasurvey1.pdf

- **Washington** prohibited the use of PFAS-containing Class B firefighting foam for training in 2018. By 2020, the manufacture and sale of these foams will be prohibited within the state, with the exceptions of the military, FAA-certified airports, petroleum refineries and terminals, and certain chemical plants.[50]

In addition, nearly half of all states have developed standards and guidance threshold values for PFOA and PFOS in drinking water and groundwater. Details on these standards and guidance values are summarized in **Exhibit 2-2** below. According to the Interstate Technology and Regulatory Council, a state-led public-private coalition formed to produce technical resources that help regulators and other stakeholders understand PFAS issues. Several states have either adopted EPA's 2016 lifetime health advisory limits (HALs) for drinking water of 0.07 µg/L for PFOA and PFOS or have chosen to use the concentrations as advisory, non-regulated levels to guide the interpretation of PFOA and PFOS detections. Other states have developed health-based values based on separate analyses of the scientific data, several of which are lower than EPA HALs:

- Vermont's lifetime combined HAL for five PFAS compounds, including PFOA and PFOS, is 0.02 µg/L.
- New Jersey has an MCL of 0.014 µg/L for PFOA and 0.013 µg/L for PFOS.
- Michigan's MCLs for PFOA and PFOS, promulgated in August 2020, are 0.008 µg/L and 0.016 µg/L respectively.

New values continue to be planned, developed, and updated across these states and others.

The state standards and guidance values are primarily for groundwater and surface water used for drinking water; however, about eleven states have developed screening levels or remedial action goals for PFOA and PFOS in soil, as detailed in **Exhibit 2-3**. Values vary by several orders of magnitude. For example, soil screening levels for protection of groundwater for PFOA range from 0.0015 mg/kg in Texas to 16 mg/kg in Delaware; screening levels for PFOS range from 0.00024 mg/kg in Michigan to 6 mg/kg in Delaware.

In all, at least 29 states either have or currently are setting standards, screening levels, and guidance values for PFOA and PFOS (and sometimes other PFAS compounds). EPA found little to no documentation of PFAS on the websites of the remaining state environmental departments and departments of health. Based on EPA's review, these state standards focus on specific state

---

Note, a search of the NY government websites, specifically the NY Department of Health and the NY Department of Environmental Conservation websites, did not yield any data on reported releases of PFAS.

[50] State of Washington Department of Ecology, "Toxics in Firefighting Law." https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/PFAS/Toxics-in-firefighting

reporting data systems, and do not include requirements for reporting to the National Response Center. They would not, therefore, offset any of the costs and benefits expected from this proposed rulemaking as states are not currently requiring entities to report releases to federal entities.[51] For further discussion of state standards and regulations pertaining to PFOA and PFOS, please refer to the preamble to the Proposed Rule.[52]

[51] Toxics Use Reduction Institute, "Per- and Poly-fluoroalkyl Substances (PFAS): Policy Analysis," May 2021. Available: https://www.mass.gov/doc/turi-pfas-policy-analysis-may-2021/download

[52] Environmental Protection Agency, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances. U.S. Environmental Protection Agency. 2022. Docket ID No. EPA-HQ-OLEM-2019-0341. https://www.regulations.gov

Exhibit 2-2
State Standards and Guidance values for PFOA and PFOS in Groundwater, Drinking Water, and Surface Water/Effluent (Wastewater)

Location	Agency / Dept	Year Last Updated	Standard / Guidance	Type	Promulgated Rule	PFOA (ppb)	PFOS (ppb)
Alaska (AK)	DEC	2016	Groundwater cleanup level	Groundwater	Yes	0.400	0.400
Alaska (AK)	DEC	2018	Action level	Drinking Water/Groundwater/Surface water and/or effluent	No	0.070	0.070
California (CA)	SWRCB	2021	Notification level	Drinking Water	No	0.005	0.007
California (CA)	SWRCB	2021	Response Level (California only)	Drinking Water	Yes	0.010	0.040
Colorado (CO)	DPHE	2018	Site-specific groundwater quality standard	Groundwater	Yes	0.070	0.070
Colorado (CO)	WQCC	2020	Translation levels	Groundwater/Surface water and/or effluent	Yes	0.070	0.070
Connecticut (CT)	DPH	2016	Private well action level	Drinking Water/Groundwater	No	0.070	0.070
Connecticut (CT)	DEEP	2018	Additional polluting substance groundwater protection criteria	Groundwater	No	0.070	0.070
Delaware (DE)	DNREC	2016	Reporting level	Groundwater	No	0.070	0.070
Delaware (DE)	DNREC	2016	Screening Level	Groundwater	No	0.070	0.070
Florida (FL)	FDEP	2019	Provisional groundwater target cleanup level	Groundwater	Other	0.070	0.070
Florida (FL)	FDEP	2019	Surface Water Screening Level	Surface water and/or effluent	Other	0.500	0.010
Hawaii (HI)	DOH	2020	Environmental action level	Protected Groundwater	Yes	0.040	0.040
Hawaii (HI)	HDOH	2021	Environmental action level	Groundwater	Other	0.040	0.040
Illinois (IL)	EPA	2021	Health-based guidance level	Drinking Water/Groundwater	Yes	0.002	0.014
Indiana (IN)	DEM	2019	Screening level (tap)	Protected Groundwater	Yes		
Iowa (IA)	DNR	2016	Statewide standards	Protected Groundwater	Yes	0.070	0.070
Iowa (IA)	DNR	2016	Statewide standards	Non-protected Groundwater	Yes	50	1
Maine (ME)	DEP	2018	Remedial action guideline	Groundwater	No	0.400	0.400
Maine (ME)	DEP	2020	Screening levels	Drinking Water	Other	0.070	0.070
Massachusetts (MA)	DEP	2018/2019	Drinking water values	Drinking Water	Other	0.020	0.020
Massachusetts (MA)	DEP	2019	Groundwater-1	Groundwater	Yes	0.020	0.020
Massachusetts (MA)	DEP	2019	Groundwater-3	Groundwater	Yes	40,000	500
Massachusetts (MA)	DEP	2020	Maximum contaminant level	Drinking Water	Yes	0.020	0.020
Michigan (MI)	EGLE	2015	Human noncancer value for surface drinking water	Surface water and/or effluent	Yes	0.420	0.011
Michigan (MI)	DHHS	2019	Screening levels	Drinking Water	No	0.009	0.008
Michigan (MI)	EGLE	2021	Maximum contaminant level/Generic Cleanup Criteria	Drinking Water/Groundwater	Yes	0.008	0.016
Minnesota (MN)	MDH	2018	HRL- subchronic	Drinking Water/Groundwater	Yes	0.035	
Minnesota (MN)	MDH	2018	HRL - chronic	Drinking Water/Groundwater	Yes	0.035	0.300
Minnesota (MN)	MDH	2019	Health-based value - subchronic	Drinking Water/Groundwater	No		0.015
Minnesota (MN)	MDH	2019	Health-based value - chronic	Drinking Water/Groundwater	No		0.015
Minnesota (MN)	MDH	2007	Health-based value	surface water and/or effluent-Lake	No		0.012
Minnesota (MN)	MDH	2007	Health-based value	Surface water and/or effluent-River	No		0.006
Montana (MT)	DEQ	2019	Water quality standard	Groundwater	Yes	0.070	0.070
Nevada (NV)	DEP	2015	Basic comparison level	Drinking Water	No	0.667	0.667
New Hampshire (NH)	DES	2019	Ambient groundwater quality standard	Groundwater	Yes	0.012	0.015
New Hampshire	DES	2020	Maximum contaminant level	Drinking Water	Yes	0.012	0.015

Exhibit 2-2 State Standards and Guidance values for PFOA and PFOS in Groundwater, Drinking Water, and Surface Water/Effluent (Wastewater)							
Location	**Agency / Dept**	**Year Last Updated**	**Standard / Guidance**	**Type**	**Promulgated Rule**	**PFOA (ppb)**	**PFOS (ppb)**
(NH)							
New Jersey (NJ)	DEP	2020	Groundwater water quality standard	Groundwater	Yes	0.014	0.013
New Jersey (NJ)	DEP	2020	Maximum contaminant level	Drinking Water	Yes	0.014	0.013
New Mexico (NM)	NMED	2019	Screening Level	Drinking Water	No	0.070	0.070
New York (NY)	DEQ	2006	Interim maximum allowable standard	Groundwater	Yes	2	
New York (NY)	DOH	2020	Maximum contaminant level	Drinking Water	Yes	0.010	0.010
North Carolina (NC)	DEQ	2006	Interim maximum allowable standard	Groundwater	Yes	2	
North Carolina (NC)	DHHS	2017	Health goal	Drinking Water	No		
Ohio (OH)	ODH	2019	Action level	Drinking Water	Other	0.070	0.070
Oregon (OR)	DEQ	2011	Initiation level	Surface water and/or effluent	Yes	24	300
Pennsylvania (PA)	DEP	2016	Medium-specific concentration	Groundwater	No	0.070	0.070
Rhode Island	DEM	2017	Groundwater quality standard	Drinking Water/Groundwater	Yes	0.070	0.070
Texas (TX)	CEQ	2021	Tier 1 PCL	Groundwater	Yes	0.290	0.560
Vermont (VT)	DEC/DOH	2020	Maximum contaminant level	Drinking Water/Groundwater	Yes	0.020	0.020
Vermont (VT)	DEC/DOH	2018	Lifetime health advisory	Drinking Water/Groundwater	Yes	0.020	0.020
Vermont (VT)	DEC	2019	Groundwater enforcement standard	Groundwater	Yes	0.020	0.020
Vermont (VT)	DEC	2019	Preventive action level	Groundwater	Yes	0.002	0.002

Exhibit 2-3
Residential Soil Standards and Guidance Values for PFOA and PFOS

State	Agency	Year Listed	Standard/Guidance	PFOA Level (mg/kg)	PFOS Level (mg/kg)
Alaska	DEC	2017	Cleanup Level	1.3	1.3
Connecticut	DEEP	2018	Additional Polluting Substance GA Pollutant Mobility Criteria	1.35	1.35
Delaware	DNREC	2021	Screening Level	0.13	0.13
Delaware	DNREC	2021	Reporting Level	1.3	1.3
Florida	FDEP	2019	Provisional Soil Cleanup Target Level	1.3	1.3
Hawaii	HDOH	2021	Environmental Action Level	0.0012	0.0075
Indiana	IDEM	2019	Screening Level	--	--
Iowa	DNR	2016	Statewide Standard	35	1.8
Maine	DEP	2018	Remedial Action Goal	1.7	1.7
Massachusetts	DEP	2019	S-1 (Soil Level 1)	0.3	0.3
Minnesota	PCA	2019	Soil Reference Value	0.24	0.041
Nebraska	DEE	2018	Remediation Goal	0.32	3.2
Nevada	DEP	2017	Basic Comparison Levels	1.56	1.56
New Hampshire	DES - EHP	2019	Direct Contact Risk-Based concentration	0.2	0.1
New Hampshire	DES - EHP	2019	Direct Contact Risk-Based concentration	1.3	0.6
New Mexico	NMED	2019	Preliminary Screening Level	1.56	1.56
New York	DEC	2020	Guidance Value	0.00066	0.00088
North Carolina	DEQ	2018	Preliminary Soil Remediation Goal	--	--
Pennsylvania	PADEP	2021	Medium-Specific Concentration	4.4	4.4
Texas	CEQ	2019	Protective Concentration Level	0.6	1.5
Texas	CEQ	2019	Protective Concentration Level	0.5	1.5
Vermont	DEC	2019	Regional Screening Level	1.22	1.22
Wisconsin	DNR	2018	Regional Cleanup Level	1.26	1.26

CHAPTER 3. COSTS, BENEFITS, AND TRANSFERS

Final designation of PFOA and PFOS as hazardous substances under Section 102(a) of CERCLA would require any person in charge of a vessel or facility that identifies a release of one pound or more of PFOA or PFOS within a 24-hour period to report the release to the NRC. Facilities will also be required to report the release to their SERC (or TERC) and LEPC (or TEPC) under EPCRA section 304. Facilities are also required to submit a follow-up written report to these entities under EPCRA section 304. Hazardous substance designation under section 102(a) of CERCLA does not lead automatically to any response actions. Response actions, which include investigations of releases of hazardous substances and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific. EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment; and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach. Furthermore, the designation of a hazardous substance under CERCLA section 102(a) in some cases does not create new costs, but rather often allows costs to be transferred from taxpayers to parties responsible for pollution under CERCLA. Even in those circumstances, where the government is authorized to transfer costs, a private party's ability to pay response costs is taken into consideration under the statute and in EPA's implementation of the statute.[53]

As such, this chapter presents the estimated annual direct costs associated with notification activity and describes the methodology used to develop these cost estimates. Due to uncertainty surrounding the number of annual releases, this analysis provides estimates under lower bound and upper bound assumptions. The chapter also includes a qualitative discussion of additional potential costs resulting from federal property sale and transfer requirements associated with the alignment of CERCLA designation with other federal regulations. Indirect costs related to potential increases in response activities and increases in the speed of response activities are qualitatively described. In addition to direct and indirect costs presented, the chapter provides qualitative discussion of direct and indirect benefits, and concludes with a qualitative review of potential transfers and redistributive impacts.

3.1 Quantified Direct Costs

This section presents the estimated annual direct costs associated with notification activity and describes the methodology used to develop these cost estimates. Due to uncertainties regarding

[53] See Memorandum from Susan Shinkman, Director, Office of Civil Enforcement, and Cynthia Mackey, Director, Office of Site Remediation Enforcement, US EPA (June 29, 2015) (Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action); Memorandum from Barry Breen, Director, Office of Site Remediation Enforcement, US EPA (Sep. 30, 1997) (General Policy on Superfund Ability to Pay Determinations).

the number of annual releases, this analysis provides estimates under lower bound and upper bound assumptions. Additionally, EPA estimates costs associated with the Hazardous Materials Transportation Act (HMTA).

3.1.1 Notification Costs per Release

The explicit reporting requirements associated with designation of PFOA and PFOS as hazardous substances include the requirement under CERCLA section 103(a) to notify the National Response Center (NRC) of a release and the requirements under EPCRA section 304 to notify the SERC (or TERC) and LEPC (or TEPC) of a release and to prepare and submit a follow-up written report.

The costs associated with notifications under CERCLA and EPCRA are documented in EPA's Information Collection Requests and Supporting Statements for those regulations, which are No. 1049, OMB No. 2050-0046 and No. 1395, OMB No. 2050-0092 respectively. **Exhibit 3-1** summarizes these per release costs; based on data in two Information Collection Request documents published by EPA, the total reporting cost for a facility submitting both telephone notifications and a written notification would be approximately $561. [54,55] Incremental detection and measurement costs are assumed to be zero or negligible, as affected facilities are likely to incur such costs in the baseline to comply with reporting requirements related to the Toxics Release Inventory (TRI). EPA assumes there will be no incremental costs to train staff on the assessment of spilled PFOA/PFOS quantities. If an entity is handling these chemicals and there is a PFOA/PFOS release at its site, we assume that it has the capability to assess spilled quantities and that its staff are sufficiently trained for this purpose. In addition, EPA assumes there will be no incremental costs associated with rule familiarization. Facilities should already be familiar with baseline requirements associated with reporting releases of non-PFOA/PFOS

[54] See EPA, Information Collection Request (ICR) No. 1049.14: Renewal of Information Collection Request for the Episodic Releases of Oil and Hazardous Substances. OMB Control No. 2050-0046, June 2018; and EPA, Information Collection Request (ICR) No. 1395.10: Statement Supporting the Renewal of the Information Collection Procedure for Emergency Planning and Release Notification Requirements. OMB Control No. 2050-0092. April 2019.

[55] As a check on this estimate, EPA made a comparison to estimates in a 1985 RIA of the costs of CERCLA reporting requirements. In 1985, EPA published an RIA examining reportable quantity adjustments under Sections 102 and 103 of CERCLA. That RIA presented unit costs for reporting and recordkeeping to regulated parties as well as notification processing to the government. In 2020$, reporting costs to regulated parties published in the 1985 RIA were between $269.06 and $718.24 depending on the quantity reported. Additionally, in 2020$, the 1985 RIA reported a unit cost of $62.48 for recordkeeping to responsible parties and $155.66 for notification processing to the government. The reporting costs per release under CERCLA and EPCRA requirements presented in **Exhibit 3-1** are within the range of the estimates published in the 1985 RIA**.**

The full citation to EPA's 1985 RIA is here: ICF. 1985. Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act. Volume 1: A Report to the Oil and Hazardous Materials Spills Branch Office of Research and Development and Environmental Response Division, Office of Emergency and Remedial Response, U.S. EPA. EPA Contract 68-03-03182

hazardous substances to the NRC and to other state and local emergency entities as required under EPCRA. EPA requests comment on expected rule familiarization costs per affected entity.

Exhibit 3-1 Reporting Costs Per Release Under CERCLA and EPCRA Requirements (adjusted to 2020$)			
	Unit Labor Cost	**Unit O&M Cost**	**Total Unit Cost**
Telephone Notification to NRC under CERCLA section 103(a)	$59.40	$0.00	$59.40
Telephone and written reporting to SERCs (or TERCs) and LEPCs (or TEPCs) under EPCRA Section 304	$495.78	$5.45	$501.23
Total	**$555.18**	**$5.45**	**$560.63**

3.1.2 Number of Annual Notifications

The expected number of reportable releases of PFOA and PFOS is not known. To estimate the number, EPA reviewed recent numbers of past release reports to the NRC of other hazardous substances. In FY 2020 the NRC received approximately 23,807 total notifications of releases of all types of hazardous substances. Of all non-oil releases reported, hazardous substances containing multiple forms of ammonia or ammonium compounds accounted for the largest number of releases in 2020; there were 660 in total. To develop an upper bound estimate for future PFOA and PFOS reportable releases, this analysis assumes that PFOA and PFOS release reports will be comparable to ammonia and ammonium release reports; that is, an upper bound assumption of 660 PFOA and PFOS notifications per year.

As a lower bound, this analysis assumes zero annual notifications of PFOA and PFOS releases. This assumption is based on EPA's 2014 *Economic Analysis of the Significant New Use Rule for Long-Chain Perfluoroalkyl Carboxylate Chemical Substances and Perfluoroalkyl Sulfonate Chemical Substances*, which suggests that PFOS and PFOA were unlikely to be manufactured, imported, or processed in the U.S. after December 31, 2015.

Toxics Release Inventory (TRI) data on PFOS and PFOA "releases" became available in 2021.[56] The current extent that any releases reported to TRI would qualify under this proposed rulemaking is unknown; TRI releases can in some cases include activities that are compliant with other regulations (e.g., pumping into an underground injection well consistent with RCRA) and would not require reporting under CERCLA. In 2020, TRI data included TRI-defined releases of PFOA or PFOS reported by nine facilities totaling 2,181 lbs. (**Exhibit 3-2**). Of the nine reports,

[56] Releases as defined for the Toxics Release Inventory under the Emergency Planning and Community Right to Know Act (EPCRA) 313 (40 CFR § 372.3) is a broad term that means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles) of any toxic chemical. However, this definition is broader than actions that would trigger a reporting requirement under this rule. For example, the 128 lb release of PFOA reported by TM Deer Park Services LP is disposal in an on-site underground injection Class I Well.

seven were at disposal facilities and two were at manufacturing facilities.[57,58] 3M's Cottage Grove Facility reported TRI-defined releases of 90 lbs. of PFOA and 77 lbs. of PFOS.

Exhibit 3-2 List of PFOA and PFOS Releases that took Place in 2020 and Reported to the Toxics Release Inventory (TRI) in 2021					
Facility Name	**Type of Facility**	**Year of Release**	**Release of Perfluorooctanoic acid (PFOA) (lbs)**	**Release of Perfluorooctane sulfonic acid (PFOS) (lbs)**	**Total Releases (lbs)**
3M Cottage Grove Center	Manufacturing	2020	90.11	76.5	166.61
Clean Harbors El Dorado LLC	Disposal	2020	475.1	0	475.1
Heritage Thermal Services	Disposal	2020	0.02	0	0.02
Vickery Environmental Inc	Disposal	2020	643.76	0	643.76
BASF Corp - Freeport Site	Manufacturing	2020	0.14	5.1	5.24
Clean Harbors Deer Park LLC	Disposal	2020	0.1	0	0.1
TM Deer Park Services LP	Disposal	2020	128	0	128
Wayne Disposal Inc	Disposal	2020	0	475.88	475.88
Clean Water Environmental LLC	Disposal	2020	0	286.7	286.7

3.1.3 Total Annual Notification Costs

This RIA estimates total annual notification costs by multiplying the estimated annual number of PFOA and PFOS notifications nationally by the estimated cost of notification per site. **Exhibit 3-3** summarizes the range of total annual notification costs. As the exhibit shows, annual notification costs are an estimated $0 to $370,000.

Exhibit 3-3 Estimated Total Annual Notification Costs (adjusted to 2020$)	
Estimated Annual Number of Notification in United States	**Estimated Notification Costs (Total)**
0 – 660	$0 - $370,000

3.1.4 Costs Associated with the Hazardous Materials Transportation Act (HMTA)

Potential direct costs may result from the DOT requirement to list and regulate CERCLA designated hazardous substances as hazardous materials under the Hazardous Materials

[57] Disposal sites were identified using NAICS code 562211 (Hazardous Waste Treatment and Disposal). 3M Cottage Grove Center and BASF Corp – Freeport Site were identified as manufacturing because BASF and 3M were listed by EPA as participants in the PFOA Stewardship Program, indicating that these sites may have been historically involved in PFOA or PFOS manufacturing. Source: Environmental Protection Agency, "Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA", 2021. Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas
[58] TM Deer Park reports to TRI under the primary NAICS code 325199 (All Other Basic Organic Chemical Manufacturing). They also report a secondary NAICS code of 562211 (Hazardous Waste Treatment and Disposal). The facility reported that they do not manufacture or process PFOA.

Transportation Act (see CERCLA Section 306(a)). EPA estimates these incremental costs as zero or negligible. It is unlikely that regulated entities would ship PFOA or PFOS in quantities equal to or above the RQ because use and production of these chemicals are understood to have been largely phased out of production and use beginning in 2000 thus the incremental shipping costs are not expected to be significant.[59] Rather, it is expected that residual quantities shipped would be commingled with other hazardous materials that are already handled and shipped as hazardous materials under the Hazardous Materials Transportation Act.

3.2 Unquantified Direct Costs

The proposed rule will create additional costs associated with CERCLA section 120(h) requirements for federal agencies to provide notice of the release of hazardous substances when selling or transferring federally-owned real property. In addition to providing notice at the time of sale, in previous sales transactions federal agencies have been required, in certain circumstances, provide a covenant warranting that "all remedial action necessary to protect human health and the environment with respect to any [hazardous substances] remaining on the property has been taken before the date of such transfer, and any additional remedial action found to be necessary after the date of such transfer shall be conducted by the United States." The number and magnitude of future federal property sales and transfers involving property contaminated with PFOA and/or PFOS is highly uncertain. Due to this uncertainty, this analysis does not attempt to quantify these costs. EPA requests comment on the number of properties that were previously transferred out of federal control with a deed that includes a covenant to provide remedial action.

3.3 Qualitative Description of Benefits

Qualitative benefits of this action include improved quality of information and a more comprehensive understanding of the number and location of sites with future releases of PFOA and PFOS which meet or exceed the RQ. This information on releases of PFOA and PFOS will enable more efficient decisions in the marketplace for nearby properties. Individuals who are more risk averse may prefer to locate farther away from sites with reported PFOA or PFOS releases relative to people who are less risk averse.

Increased data disclosure regarding individual companies' releases may also reduce uncertainty in capital markets. The value of this reduced uncertainty may be reflected in the market capitalization or cost of capital of affected firms. These changes represent a benefit to society because they allow financial capital to be allocated more efficiently than under baseline

---

[59] Environmental Protection Agency (U.S. EPA). Technical Fact Sheet -- Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA). 2017. Accessed online Sept. 2021: https://www.epa.gov/sites/default/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf

conditions, thereby expanding the productive capacity of the economy. For example, a study by Campbell et al. analyzes the relationship between environmental liability uncertainty, specifically Superfund liabilities, and a firm's market valuation (market value of common stock).[60] Focusing on the chemical, paper, and machinery industries, Campbell et al. found that significant uncertainty in a firm's Superfund liabilities could reduce its market value by more than $4 per share per site in the sample, though this result varied significantly across industries.

Other direct benefits associated with the proposed rule's reporting requirements could include better waste management practices for facilities handling PFOA or PFOS in an effort to avoid releases of these substances into the environment. Incentivizing the prevention of releases is expected to decrease potential threats to public health and welfare and the environment. Several studies have shown that increased transparency regarding environmental releases is associated with reductions in releases. Focusing on toxics releases that became subject to disclosure following passage of the Emergency Planning and Community Right to Know Act in 1986, Konar and Cohen found that firms with the largest decline in stock price following disclosures of their environmental releases through the Toxics Release Inventory (TRI) reduced their releases more than their industry peers.[61] Similarly, and also focused on TRI, a subsequent study by Konar and Cohen found that disclosure requirements led to the most significant reductions in releases among firms that were most visible to the public.[62] Examining repeated public disclosures of releases by firms in the chemical industry between 1990 and 1994, Khanna et al. concluded that repeated provision of release data led to reductions in stock price, which then had a significant negative impact on subsequent toxic releases from these sites.[63]

Requiring that releases of PFOA and PFOS be reported may improve the speed and design of any subsequent cleanups (both privately and publicly funded), thereby potentially reducing risks and conferring benefits earlier. For example, the reporting of a release could potentially raise community awareness of a release and accelerate a privately-financed voluntary cleanup. This could more quickly reduce risks faced by nearby exposed individuals.

These actions are discretionary and dependent on various factors that are challenging to predict, but, depending on local site conditions and technology options, may include averting actions or requirements for remediation.

---

[60] Katherine Campbell, Stephan E. Sefcik, and Naomi S. Soderstrom (1998), "Site uncertainty, allocation uncertainty, and superfund liability valuation," Journal of Accounting and Public Policy, Vol. 17 (1998): 331-366.
[61] Shameek Konar and Mark A. Cohen. (1997), "Information As Regulation: the Effect of Community right to Know Laws on Toxic Emissions," Journal of Environmental Economics and Management, Vol. 32, pp. 109-124.
[62] Shameek Konar and Mark A. Cohen. (2000). "Why do Firms Pollute (and Reduce) Toxics Emissions?", unpublished working paper, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=922491.
[63] Khanna, Madhu, Wilma Rose H. Quimio, and Dora Bojilova. (1998). "Toxics Release Information: A Policy Tool for Environmental Protection," Journal of Environmental Economics and Management, Vol. 36(3): 243-266.

3.4 Qualitative Discussion of Indirect Costs, Benefits, and Transfers

The proposed designation of PFOA and PFOS as CERCLA hazardous substances may lead to benefits and costs from potential indirect impacts on assessment and response activities. Transfers of costs from the public to responsible parties may also occur contingent upon statutory requirements being met, and discretionary actions by EPA. Consistent with the guidance of Office of Management and Budget's (OMB's) Circular A-4, further economic considerations are included to provide the public with insights related to indirect costs, benefits, and potential transfers of liability.

3.4.1 Indirect Costs including Cost Savings

To the extent that the Proposed Rule shifts the response burden from EPA to potentially responsible parties (PRPs) in the private sector, response and clean-up may be less costly than under baseline conditions. When CERCLA was passed, one of the reasons for establishing a hybrid system in which PRPs themselves implement many cleanups was to harness the efficiency and expertise of the private sector.[64] If the private sector is able to complete cleanups for sites contaminated with PFOS or PFOA more efficiently than the public sector, the costs of site clean-up may decline relative to baseline.

In addition to the potential for notification requirements of releases of PFOA and PFOS to NRC to improve the speed of response actions (both privately and publicly funded), EPA's improved authority to transfer response costs to PRPs may also enable more efficient response to PFOA and PFOS than under baseline authority to respond to PFOA and PFOS as pollutants and contaminants. Earlier response activity is generally considered to be more cost efficient, in that containing and removing more concentrated contamination is more cost efficient than addressing contamination that over time has spread to a greater area. For instance, it may be more cost effective to respond to one highly contaminated property before contamination spreads than multiple properties with lower contamination levels that resulted from migration of an earlier contamination event. PFOA and PFOS are both known to be mobile and persistent chemicals in the environment and contaminated soil has been shown to result in groundwater plumes that grow in size over time. More prompt cleanup is also likely to reduce response costs associated with providing alternate drinking water supplies because fewer households will be in need.

At least partially offsetting these cost savings, earlier response activity (all else equal) will increase the costs of clean-up in present value terms. Whether the net impact of earlier response

---

[64] Katherine N. Probst (2020). "Superfund at 40: Unfulfilled Expectations", in Looking Back to Move Forward: Resolving Health & Environmental Outcomes, edited by Hampden T. Macbeth. State Energy & Environmental Impact Center, New York University Law School.

is an increase or decrease in costs is uncertain and will depend on the relative magnitude of these competing effects.

The rule may also result in increased research and development (R&D) expenditures to ensure the effective removal of PFOA and PFOS. The need for these R&D expenditures is unclear, however. For example, it is uncertain how those wastewater treatment plants needing to treat high levels of PFOA and PFOS would remove them from wastewater treatment sludge. Depending on whether incineration (an existing technology) is effective for the removal of PFOA and PFOS from wastewater treatment sludge without creating harmful products of incomplete combustion, additional R&D expenditures may or may not be necessary to ensure effective removal. R&D costs have been included in past EPA RIAs. For example, the RIA for the 2017-2025 light-duty vehicle greenhouse gas emission standards and corporate average fuel economy standards estimated R&D costs through the use of indirect cost multipliers.[65] EPA requests comment on the R&D expenditures that may be necessary to ensure effective removal of PFOA and PFOS.

Another potential indirect impact of this proposed designation may include an impact on the number of sites identified, assessed, and/or remediated. However, the incremental change in the total number of such sites is unknown due to a lack of data. Therefore, it is not feasible to quantify the associated costs. See Section 3.7 for discussion about the nature of indirect costs and Section 3.8 for a description of uncertainties and analytic limitations.

3.4.2 Indirect Benefits

Requiring notification of releases of PFOA and PFOS to NRC may improve the speed of subsequent response actions (both privately and publicly funded), thereby reducing risks and conferring health and other social benefits earlier. For example, the reporting of a release could raise community awareness of a release and accelerate a privately-financed voluntary cleanup. This may reduce risks faced by nearby exposed individuals more quickly.

EPA expects that response actions would occur more rapidly than under the baseline situation. Under the baseline, a determination that the detected levels of PFOA and/or PFOS may present imminent and substantial danger would be required along with the commitment of government funding to pay for response. Responding to contaminated sites sooner lessens environmental exposures over time and thereby reduces the cumulative impacts on human health and the environment.[66]

---

[65] U.S. EPA, *Regulatory Impact Analysis: Final Rulemaking for 2017-2025 Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards*, EPA-420-R-12-016, August 2012.
[66] *Ibid.*

The proposed designation may also lead to an incremental increase in the number of contaminated sites identified, assessed, and remediated. Thus, in addition to an indirect potential effect of speedier cleanups, benefits may be experienced due to additional sites being addressed.

The benefits of reduced PFAS exposure vary, but research has shown that exposure to PFOA and PFOS may lead to the following adverse health effects: high cholesterol, changes in increased liver enzymes, decreased immune response to vaccination, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer. Exposure to PFOA may also lead to fetal growth restriction (reduced birth weight). A more detailed discussion of the health effects associated with PFOA and PFOS exposure is included in the Preamble of the Notice of Proposed Rulemaking.[67] Speedier identification, assessment, and response activities addressing PFOA and PFOS exposures are expected to reduce the associated health effects on nearby populations. The nature of response actions that may induce the described indirect benefits are dependent on various factors that are challenging to predict, but, depending on local site conditions and technology options, may include averting actions or requirements for response. CERCLA cleanups are conducted when site-specific risk assessments identify potential environmental or human health risks. To the extent that the proposed designation reduces the risks of these adverse health effects, this will lead to a health care cost savings.

The health benefits related to reduced exposure to PFOA and PFOS may be realized by multiple segments of the population. To the extent that individuals who realize these benefits participate in the labor force, the reduction in exposure to PFOA and PFOS would potentially lead to improvements in worker productivity. In general, the number of sick days among workers who are healthy is lower than the number of sick days among workers who are not healthy. While at work, healthier employees are generally more productive. Thus, pollution reduction at sites affected by PFOA or PFOS where people are exposed is likely to improve productivity for those exposed individuals who are work force participants. A small but growing literature addresses the relationship between air pollution and worker productivity.[68]

As described in Section 3.6.1, the proposed rule may result in R&D expenditures to develop more effective removal methods for PFOA and PFOS. A potential benefit of these expenditures is that removal may become more efficient. The need for R&D and subsequent magnitude of

[67] Environmental Protection Agency, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances. U.S. Environmental Protection Agency. 2022. Docket ID No. EPA-HQ-OLEM-2019-0341. https://www.regulations.gov.

[68] See Joshua Graff Zivin and Matthew Neidell, "Air pollution's hidden impacts: Exposure can affect labor productivity and human capital," *Science*. Vol. 359, Issue 6371, January 5, 2018; Joshua Graff Zivin and Matthew Neidell, "Environment, Health, and Human Capital," NBER Working Paper 18935, April 2013; and Joshua Graff Zivin and Matthew Neidell, "The impact of Pollution on Worker Productivity," *American Economic Review.* Vol. 102(7): 3652-3673, 2012.

related benefits, however, are uncertain. EPA requests comment on any R&D-related benefits that may result from the Proposed Rule.

In addition to the indirect benefits described above, the clarification of reporting responsibilities, and earlier responses to contamination, could indirectly contribute to more efficient litigation (e.g., by reducing public entities burden of proof requirements related to contamination). To the extent that this occurs, funds that would have been used for related litigation can be redirected to expand or improve other publicly funded goods and services.

3.4.3 Transfers

This proposed rulemaking is one step towards potential PFOA and PFOS response cost recovery for EPA, and allows EPA to respond to PFOA and PFOS contamination without making a potential imminent and substantial danger finding. However, the proposed designation does not require EPA to take response actions, does not require any site-specific response action by a private party, and does not determine liability for hazardous substance release response costs. In the baseline, if EPA sought to initiate a response action, the Agency could use its authority under CERCLA section 104(a) for pollutants and contaminants if a release or threatened release may present an imminent and substantial danger to the public health or welfare. When the EPA responds to a release or threat of a release of a pollutant and contaminant under Section 104, the US Government (i.e., the taxpayer) incurs the costs and does not have the authority to recover those costs from responsible parties. This is because the costs of response to address a substance under CERCLA Section 107 are only recoverable if the substance is a “hazardous substance.” The proposed rule would designate PFOA and PFOS as hazardous substances under Section 102, which would enable EPA to recover its costs of response from responsible parties – i.e., transfer the cost of its response from the taxpayer to a liable party. Thus, an important indirect impact of the proposed designation is to transfer the costs of potential response activities from the public to polluters. The potential in some instances to affect liability in a way that would transfer response costs from taxpayers to polluters is not considered a cost (either direct or indirect) resulting from the proposed rule.[69] A qualitative discussion of the nature of potential transfers associated with future discretionary response decisions is presented below (see Section 3.6.4)

In addition to having the capability in the baseline to address PFOA and PFOS with a potential imminent and substantial danger finding, there is another important circumstance when PFOA and PFOS contamination can be addressed in the baseline. To the extent PFOA or PFOS are

---

[69] ‘Costs’ affect the total resources available to society. ‘Transfers’ are monetary payments from one group to another that do not affect total societal resources. Office of Management and Budget, “Regulatory Impact Analysis: Frequently Asked Questions,” February 7, 2011, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/OMB/circulars/a004/a-4_FAQ.pdf

commingled with releases of hazardous substances at facilities, EPA and other agencies exercising delegated CERCLA authority may require the responsible party to address such releases. If this proposed designation is finalized, a broader range of response authority could be applied. EPA and other agencies exercising delegated CERCLA authority, may respond to PFOA or PFOS without making a finding that the substances may present imminent and substantial danger, may require the responsible party to address a release, and may seek contribution or recovery of costs incurred for their response actions, contingent on other relevant statutory criteria being met. The above actions are considered transfers and may apply to releases that occurred prior to finalizing the Proposed Rule as well as after promulgation of a Final Rule.

3.5 Uncertainties Regarding Indirect Impacts on Response Activities

Significant uncertainty about the extent of existing PFOA and PFOS use and contamination, evolving assessment and response technologies, and health science pose outstanding barriers to developing a robust quantitative analysis of the indirect costs, benefits, and potential transfers associated with response to PFOA and PFOS contamination under CERCLA. This section describes some of those uncertainties in detail and provides further insight into the analytical limitations preventing quantitative analysis. EPA requests comment on uncertainties regarding the unquantifiability of indirect cost, benefit, and transfer impacts as described below.

EPA is not aware of any peer reviewed literature on systematic examination of liability, management, and cleanup costs associated with PFOA and PFOS contamination. There are several peer-reviewed journal articles providing perspectives on this topic.[70,71] However, none of the articles that EPA is aware of provide quantitative data expressly for PFOA and PFOS, but rather provide insight about possible costs of liability, management, and cleanup associated with PFAS, defined in each article as a class of over 9,000 chemicals. These articles do not provide information about costs specific to distinct response activities, the number of sites for testing and remediation, the level of remediation, types and/or quantities of environmental media considered for remediation, or other details that would be useful in conducting robust quantitative cost and benefit analysis. In addition, these works do not provide enough information on regulatory structure to inform attribution of costs. Attribution of costs is an important consideration due to ongoing work at State and Federal levels. Given the lack of information and systemic analysis of remediation of PFOS and PFOA, we seek information and comment that may allow EPA to estimate incremental indirect costs associated with this rule.

---

[70] See for example: Ross, I., McDonough, J., Miles, J., Storch, P., Thelakkat Kochunarayanan, P., Kalve, E., Hurst, J.; S. Dasgupta, S., Burdick, J. A review of emerging technologies for remediation of PFASs. Remediation 2018, 28 (2), 101−126.

[71] See for example: Kwiatkowski, C. F., Andrews, D. Q., Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. Environmental science & technology letters, 7(8), 532–543. https://doi.org/10.1021/acs.estlett.0c00255

While data specific to PFOA and PFOS remediation are limited, a 2019 EPA Market Study provides some context for remediation costs associated with other hazardous substances at non-federal NPL sites. The NPL is the list of sites of national priority among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States and its territories. The NPL is intended primarily to guide the EPA in determining which sites warrant further investigation. Based on the 2019 study, historical average total site costs to address all hazardous substances across all sites on the NPL (inclusive of all contamination types and sources) equals between $35.2 and $48.2 million per site[72] These costs are provided for reference, and it is unknown how they would relate or compare to costs associated with response actions addressing PFOA and PFOS at a contaminated site. For instance, PFOA and PFOS present at a site with other hazardous substances may be addressed with treatment methods used for other hazardous substances, in which case addressing PFOA and PFOS risks would not result in additional response costs above the baseline. Some examples of these treatment methods include granular activated carbon (GAC) filtration, incineration, and the removal/landfilling of contaminated media.[73] In instances where PFOA and/or PFOS contamination are at levels that present a risk absent other hazardous substances, examples of costs associated with a response action would be dependent on the extent of contamination, the cleanup level needed to manage the risks associated with the contamination, and the treatment technology available.

3.5.1 Uncertainties Regarding the Number of Potential Sites Indirectly Affected

EPA lacks information on the number of sites that may require response actions to address past PFOA or PFOS releases. Although the entities that have historically used PFOA and PFOS are described in Chapter 2, the specific sites contaminated with these chemicals is unknown. **Exhibit 2-1** summarizes users and associated products that, based on historical use, may contain PFOA and PFOS.

Although this EA lacks adequate data to comprehensively identify and assess the number of sites affected by the proposed rule, there are data available that provide insights into EPA's current understanding of the baseline extent of PFOA and PFOS contamination. One source of data resulted from EPA collecting information on the occurrence of PFOA and PFOS at National Priorities List (NPL) sites. A total of 175 sites recorded both PFOA and PFOS detection, 3 sites recorded only PFOS detection, and 6 sites recorded only PFOA detection. It is important to note that this list is a preliminary indicator of potential contamination and the existence of a PFOA or PFOS detection at a site is the first in a series of subsequent, contingent steps from a determination that a response action may be necessary to address the chemicals.

---

[72] Environmental Protection Agency. "542-R-19-002: 2019 Remediation Market Study". January 15, 2020.
[73] Interstate Technology and Regulatory Council, "12 Treatment Technologies". August 2021. Available at: https://pfas-1.itrcweb.org/12-treatment-technologies/#12_3.

Additionally, the use of Aqueous Film-Forming Foam Concentrates (AFFF) at airports is a potential source of site contamination. The National Plan of Integrated Airport Systems (NPIAS) public facing dataset presented by the Federal Aviation Administration (FAA) estimates that there are 3,314 airports across the US; it is unknown how many of these airports have experienced AFFF releases. Using SEMS data, 48 NPL sites with a PFAS detection are located at airports, though the majority of these sites are located at military installations and may not be representative of operations at commercial airports.[74]

The existence of PFOA or PFOS detections or use at a site does not necessarily imply that further evaluation is needed or would result in a determination that a response action is warranted. The universe of sites that have PFOA or PFOS contamination that warrants response action under CERCLA is indeterminable due to lack of site-specific information and standards for cleanup.

3.5.2 Uncertainties Regarding Cleanup Standards

Exhibits 2-2 and 2-3 provide examples of state and residential standards used to evaluate PFOA and PFOS levels in water and soil, and additional scientific reviews that may inform future standards.[75] To date, site remediation has been focused on sites of specific concern to various states and localities, with varying cleanup objectives. Associated costs may therefore reflect fluctuating levels of concern or types of sources; specific-site remediation activity may or may not be representative of potential sites, in scope or cost, indirectly affected by the proposed rule. The lack of data about the number and types of sites requiring assessment and the specific costs associated with required assessments and response activities prevents quantitative assessment of response costs.

There is significant uncertainty surrounding additional and future impacts associated with development of/changes in federal cleanup standards to reflect changes to toxicity values for PFOA and PFOS. Absent a change in reportable quantities, these would not affect the direct costs of the Proposed Rule or the sites affected by the Proposed Rule, but they would ultimately affect indirect response costs, benefits, and potential transfers. The associated impacts resulting from developments and/or changes in federal cleanup standards are noted here for awareness but would be attributable to those subsequent rulemakings specifying such standards.

- Appropriate site remedies and associated costs, benefits, and transfers are determined in part by the response standards in place. As these emerge and evolve at the federal level, anticipated remedies and costs may change. Moreover, current state requirements vary and may change, affecting the selection of technologies.

---

[74] Environmental Protection Agency. "Superfund Enterprise Management System (SEMS). February 2022.
[75] https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601

- The number and type of sites and environmental media requiring response action might also be affected as cleanup standards emerge at both the federal and state level.

3.5.3 Uncertainties Regarding Assessment and Cleanup Technologies and Associated Costs

The evolving understanding of technology used to assess and respond to various PFOA- or PFOS-contaminated media at sites introduces further uncertainty in developing a quantitative estimate of the cost of response actions associated with the designation of PFOA and PFOS as hazardous substances under CERCLA section 102(a). Treatment and disposal technologies for PFOA and PFOS are changing, and the associated costs of implementing these technologies vary significantly based on geographic location, partly due to transportation costs and access to treatment and disposal facilities.

Numerous research efforts on PFOA and PFOS dedicated to risk assessment methods and advancing remediation technology options are underway and new information is regularly made available in this regard. Examples of such efforts include the following: Department of Defense environmental research programs include the Strategic Environmental Research and Development Program (SERDP) and the Environment Security Technology Certification Program (ESTCP). These programs have sponsored research on addressing PFAS contamination and information about the research is available on their website.[76] EPA's Office of Research and Development has conducted and sponsored a number of studies to advance the understanding of PFAS treatment, disposal, toxicity, and environmental fate and transport and much of this research is ongoing.[77] In addition, the Contaminated Site Cleanup Information Web Site (CLU-IN.org) publishes information about advances in technology across the hazardous waste remediation community, including developments in treatment options for PFAS.

Finally, the incremental cost of addressing PFOA and PFOS relative to baseline costs of treating other contaminants on existing contaminated sites is unknown. PFOA and PFOS present at a site with other hazardous substances may be addressed with treatment methods used for other hazardous substances, in which case addressing PFOA and PFOS risks would not result in additional response costs above the baseline.

3.5.4 Summary of the Process and Associated Costs for Determining Response Efforts

The following information provides an overview of the process of determining whether response may be warranted at a site, and the associated methods that might be employed if a need is identified:

---

[76] https://serdp-estcp.org/About-SERDP-and-ESTCP
[77] https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas

- **Sampling.** For sites on the NPL, EPA may take samples to determine whether a PFOA and/or PFOS release requires additional investigation or action.[78]

- **Additional investigations and feasibility studies.** Once media have been sampled, additional data are gathered at the site. A feasibility study is also conducted that develops and evaluates options for remedial actions.[79]

- **Remediation efforts.** A remedial design plan is developed to address contaminated media. Contaminated soil is removed, treated, and/or disposed. Contaminated groundwater is pumped and/or treated; successful water treatment technologies include activated carbon adsorption, ion exchange resins, and high-pressure membranes. Water cleanup activities can also include installing water treatment facilities, providing alternative drinking water, shutting down drinking water wells, and connecting homes with private wells to municipal water systems.[80]

With regard to the potential for new sites to be added to the NPL due to PFOA or PFOS contamination, before EPA adds a new site to the NPL, the site must meet EPA's requirements and be proposed for addition to the list in the Federal Register, subject to a 60-day public comment period.[81] Response actions, which include investigations of releases of hazardous substances and determining if removal or remedial action is necessary, are contingent, discretionary, and site-specific. EPA prioritizes the highest-risk sites under CERCLA (and that listing process is open to public comment); the process for selecting remedies includes public notice and comment; and cost considerations, among other important factors such as protectiveness, are part of CERCLA's site-specific cleanup approach. The associated impacts resulting from newly added sites to the NPL are noted here for awareness but would be attributable to those subsequent final rulemakings listing individual sites.

[78] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[79] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[80] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[81] Over the last decade, from January 2012 through December 2021, the average number of new sites added to the NPL is about 12 sites per year. This number varies widely by year, with the lowest number (4) of new sites listed in 2021, and the highest number (23) of new sites listed in 2012. https://www.epa.gov/superfund/national-priorities-list-npl-sites-listing-date

The Department of Defense (DOD) has also released cost estimates associated with PFAS response efforts at military sites, not specific to PFOA or PFOS.[82,83] It is important to note that these estimates represent one cost point for potential PFAS response costs specifically focused on applications related to national defense. It is possible the PFAS costs released by DOD are not representative of other sites as the types, quantity, and handling of PFAS are expected to vary greatly. An equally important consideration to note associated with DOD cost estimates is that the EPA expects the size and scope of, and therefore costs associated with, federal PFOA or PFOS cleanup sites to be substantially larger than non-federal sites.

DOD reports that it has incurred $1.1 billion in investigation and cleanup costs for PFAS through fiscal year 2020; future remediation costs, or costs after fiscal year 2020, will exceed $2.1 billion.[84] As of 2020, DOD has identified 687 sites with a known or suspected release, including 328 Army installations, 149 Navy installations, 203 Air Force installations, and seven Defense Logistics Agency installations.[85] DOD provides an additional breakdown of its annual obligations between fiscal years 2018 and 2021 in its *2021 Report to Congress:*[86]

> *DoD obligated $204.5 million to investigate and $124.3 million to clean up PFAS through the end of FY 2018. DoD obligated an additional $51.9 million for investigations and $120.8 million for cleanup of PFAS in FY 2019. In FY 2020, DoD planned to obligate $70.8 million and $40.6 million to investigate and clean up PFAS, respectively; DoD's actual obligations were $242.5 million and $28.3 million, respectively. DoD plans to obligate $56.4 million to investigate and $39.9 million to clean up PFAS in FY 2021. After FY 2021, DoD estimates that it will obligate $442.8 million to investigate and $318.1 million to clean up PFAS. The appendix provides these obligations by DoD Component and installation.*
>
> *DoD does not track funding by contaminant and, as such, the data presented in the appendix represents the DoD Components' best estimates of the funding obligated and to be obligated for investigations and cleanup of DoD releases of PFAS. The planned obligations are as of the end of FY 2020 and may change based on the FY 2021*

---

[82] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[83] Department of Defense: Office of the Under Secretary of Defense for Acquisition and Sustainment. "Per-and Polyfluoroalkyl Substances Cleanup Costs". July 2021.
[84] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[85] United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.
[86] DOD presents obligations for 582 sites in its 2021 Report to Congress, but GAO-21-421 identifies 687 total sites with a known or suspected PFAS release. The cause of this discrepancy is unknown.

Appropriations Act. Additionally, based on current information, DoD estimates obligations for beyond FY2021 to exceed $1 billion for active installations and National Guard locations as reported here, for a total of $2.1 billion including Base Realignment and Closure sites. DoD expects this estimate to increase as the DoD Components complete the initial assessments and additional information is known about the extent of the cleanup required. The DoD Components will plan and program for these requirements as they are defined.[87]

Estimates of DoD cost obligations to date are both imperfect and partial, as noted by DoD, and it is not clear whether spending for a site is proportional to the extent of contamination or risk. To date, 64 percent of DoD's investigation and cleanup cost obligations are allocated to sites operated by the Air Force or the Air National Guard, suggesting that one of DoD's areas of focus has been on aviation applications.

3.5.5 Summary of Critical Uncertainties Regarding Indirect Impacts on Response Activities

Some of the key critical uncertainties affecting the feasibility of generating quantitative estimates of costs, benefits, and potential transfers associated with response actions for PFOA and PFOS contamination, and more specifically, the indirect impact of the Proposed Rule, if any, on assessment and response activities are provided here. These include:

- Limited data from PRPs and EPA specifically documenting the incremental costs and benefits of PFOA and PFOS cleanup.
  - EPA does not know each of the sites contaminated by PFOA and/or PFOS.
  - EPA does not have record of the cost of assessment and cleanup at sites contaminated by PFOA and/or PFOS. Thus, there is no estimate of the magnitude of costs and benefits associated with response actions.
- Limited data are available from PRPs and EPA specifically documenting the incremental cost of PFOA and PFOS cleanup when other hazardous substances are also present. The extent to which PFOA and PFOS contamination co-occur with other substances complicates cost estimates in several ways, including:
  - Incremental costs for assessing the extent of PFOA and PFOS contamination are not well documented or specified to date, but may be limited or reduced in context with multiple pollutants.

[87] Department of Defense: Office of the Under Secretary of Defense for Acquisition and Sustainment. "Per-and Polyfluoroalkyl Substances Cleanup Costs". July 2021.

- Response costs related to PFOA and PFOS may also be affected by other contaminants. For example, treatment for other hazardous substances comingled with PFOA and PFOS may be effective at responding to PFOA and PFOS. Alternatively, consideration of PFOA and PFOS in combination with other contaminants may result in selection of different response methods to optimize site-wide cost effectiveness. Data are not readily available to quantitatively assess these impacts at a level beyond anecdotal examples.

CHAPTER 4. ECONOMIC IMPACTS ANALYSES RESPONSIVE TO STATUTORY AND EXECUTIVE ORDERS

As required by applicable statutes and executive orders, this chapter summarizes our analysis of equity considerations and other regulatory concerns associated with the proposed rule. This chapter assesses potential impacts, with respect to the following issues:

- **Energy impact:** considers the potential for this proposed rule to affect the supply, distribution, or use of energy, including changes in the price of fuel.
- **Regulatory flexibility:** considers the potential for rule-related costs to have a significant impact on a substantial number of small entities (SISNOSE).
- **Minority and low-income populations:** considers the potential for the proposed rule to have disproportionate impacts on minority or low-income populations.
- **Children's health:** considers the potential for the proposed rule to have a significant or disproportionate impact on the health of children.
- **Regulatory planning and review:** requires examination and quantification of costs and benefits of regulating with and without the proposed rule.
- **Unfunded mandates:** examines the implications of the proposed rule with respect to unfunded mandates imposed on state, local, and tribal governments.
- **Federalism:** considers potential issues related to state sovereignty.
- **Tribal governments:** extends the discussion of federal unfunded mandates to include impacts on Native American tribal governments and their communities.
- **Employment:** considers potential impacts on employment resulting from the compliance costs associated with reporting.

4.1 Energy Impact Analysis

Executive Order 13211, "Actions Concerning Regulations that Affect Energy Supply, Distribution, or Use" (May 18, 2001), addresses the need for regulators to consider the potential energy impacts of the proposed rule and resulting actions. Under Executive Order 13211, agencies are required to prepare a Statement of Energy Effects when a regulatory action may have significant adverse effects on energy supply, distribution, or use, including impacts on price and foreign supplies. Additionally, the requirements obligate agencies to consider reasonable alternatives to regulatory actions with adverse effects and the impacts that such alternatives might have on energy supply, distribution, or use.

This action is not a "significant energy action" under Executive Order 13211 because it is not related to, or likely to have a significant adverse effect on, the supply, distribution or use of energy.

4.2 Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 USC 601 et seq., generally requires EPA to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute. This analysis must be completed unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If a regulation is found to have a significant impact on a substantial number of small entities, further analysis must be performed to determine what can be done to lessen the impact. Small entities include small businesses, small organizations, and small governmental jurisdictions. EPA developed a screening analysis and supplemental analysis consistent with the requirements under RFA.

For purposes of assessing the impacts of this rule on small entities, a small entity is defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR Part 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. EPA typically considers costs in excess of one percent and three percent of revenues as indications that the proposed rule may have a significant impact on a given small entity including businesses and governments, and estimates of greater than 20 percent of total small firms or 1,000 total small firms affected as indications that a substantial number of small entities may be affected by the proposed rule. The following sections consider these thresholds.

4.2.1 Associated Cost of Proposed Rule

The explicit reporting requirements associated with designation of PFOA and PFOS as CERCLA hazardous substances include the reporting requirements for episodic releases of hazardous substances found in CERCLA section 103(a), and the reporting requirements under EPCRA section 304. The reporting activities are:

- Telephone notifications to the NRC, SERC (or TERC), and LEPC (or TEPC); and
- Preparation and submission of a written notification report to the SERC (or TERC) and LEPC (or TEPC).

The costs associated with notification under CERCLA and EPCRA are documented in EPA's Information Collection Requests and Supporting Statements for those regulations, which are No.

1049, OMB No. 2050-0046 and No. 1395, OMB No. 2050-0092 respectively. Additionally, this proposed rulemaking considers additional costs related to federal property transfer requirements associated with the alignment of CERCLA designation with other federal regulations. As discussed in previous sections, the latter costs are currently unable to be estimated due to the lack of information about the number and locations of PFOA and PFOS releases meeting or exceeding the reportable quantity (RQ). This analysis assumes that a given facility will experience no more than one such release per year. **Exhibit 3-1** above summarizes these per release costs. The total reporting cost for a facility submitting both a telephone and written notification would be roughly $561.

4.2.2 Revenues of Impacted Small Entities

To estimate the annual breakeven costs per facility, the analysis relies on three pieces of information for each industry: (1) average annual revenues per small entity, (2) average number of facilities per small entity, and (3) the target breakeven percentage of costs to revenues (either one percent or three percent) at both the entity and facility level. While regulatory flexibility determinations focus on entity revenues and not single facilities, uncertainty about the facilities potentially affected and the limitations of the breakeven analysis format make it useful to examine the breakeven values at both an entity and facility level, to reflect the possibility that all locations of an entity (e.g., a car wash) could operate in similar ways and report similar releases.

Exhibit 4-1 shows the estimated breakeven costs per small entity (firm or government) and facility, by industry.[88] These results are presented using six-digit NAICS codes.[89] Estimated annual breakeven costs per facility are lowest for Car Washes (NAICS 811192). Estimated breakeven costs are next lowest at Sewage Treatment Facilities (NAICS 221320) with annual costs of $12,786 meeting the one percent revenue threshold, followed by Commercial Printing - except Screen and Books (NAICS 323111) and Other Airport Operations (NAICS 488119) with annual costs meeting the one percent threshold of $21,930 and $22,239, respectively. Estimated annual breakeven costs for all other industries are greater than $25,000 at the one percent revenue threshold.

While EPA did evaluate potential revenue impacts on Sewage Treatment Facilities (NAICS 221320), it did not analyze impacts on small municipal drinking water utilities because these entities were not identified as potential sources of major PFOA or PFOS releases (see Chapter 2 for full discussion of the universe identified for analysis). EPA does not currently have data on

[88] This analysis estimates the number of small entities per industry by integrating the SBA size standards with industry profile data from the United States Census Bureau's 2017 Statistics of U.S. Businesses (SUSB).
[89] The NPRM lists the following three-digit NAICS codes as containing potentially relevant entities: 324 - Petroleum Refining Industry, 325 - Chemical Manufacturing Sector, and 562 - Waste Management and Remediation Services; relevant six-digit NAICS codes within these sectors are captured in **Exhibit 4-1**.

the number or extent of potential releases by small governmental entities, and requests comment on the associated impacts to small municipal drinking water utilities from the proposed rule.

Exhibit 4-1 Breakeven Estimates for Annual Costs per Facility (adjusted to 2020$)							
Industry	NAICS Code and Description	Annual Revenues per Small Entity [a]	Average Number of Facilities per Small Entity [b]	Breakeven Annual Cost per Entity: 1% Threshold [c = (1% × a)]	Breakeven Annual Cost per Entity: 3% Threshold [d = (3% × a)]	Breakeven Annual Cost per Facility: 1% Threshold [e = (1% × a)/b]	Breakeven Annual Cost per Facility: 3% Threshold [f = (3% × a)/b]
Aviation operations	488119 - Other Airport Operations	$2,537,912	1.11	$25,379	$76,137	$22,939	$68,818
Carpet manufacturers	314110 - Carpet and Rug Mills	$8,527,078	1.05	$85,271	$255,812	$81,335	$244,006
Car washes	811192 - Car Washes	$569,439	1.07	$5,694	$17,083	$5,313	$15,939
Chrome electroplating, anodizing, and etching	332813 - Electroplating, Plating, Polishing, Anodizing, and Coloring	$3,194,451	1.04	$31,945	$95,834	$30,704	$92,111
Coatings, paints, and varnish	325510 - Paint and Coating Manufacturing	$8,579,550	1.08	$85,796	$257,387	$79,697	$239,090
Firefighting foam manufacturers	325998 - All Other Miscellaneous Chemical Product and Preparation Manufacturing	$9,615,850	1.06	$96,159	$288,476	$91,107	$273,322
Landfills	562212 - Solid Waste Landfill	$2,732,229	1.02	$27,322	$81,967	$26,744	$80,231
Medical Devices	339112 - Surgical and Medical Instrument Manufacturing	$10,924,915	1.05	$109,249	$327,747	$104,317	$312,950
Municipal fire departments and firefighting training centers	922160 - Fire Protection	N/A	N/A	N/A	N/A	N/A	N/A
Paper mills	322121 - Paper (except Newsprint) Mills	$109,190,104	1.28	$1,091,901	$3,275,703	$851,896	$2,555,688
	322130 - Paperboard Mills	$53,571,512	1.08	$535,715	$1,607,145	$495,518	$1,486,553
Petroleum refineries and terminals	324110 - Petroleum Refineries	$919,097,728	1.16	$9,190,977	$27,572,932	$7,948,953	$23,846,860
	424710 - Petroleum Bulk Stations and Terminals	$54,054,028	1.21	$540,540	$1,621,621	$445,151	$1,335,452
Pesticides and Insecticides	325320 - Pesticide and Other Agricultural Chemical Manufacturing	$25,079,234	1.06	$250,792	$752,377	$236,296	$708,887
Photographic film manufacturing	325992 - Photographic Film, Paper, Plate, and Chemical Manufacturing	$3,410,199	1.05	$34,102	$102,306	$32,595	$97,784
Polishes, waxes,	325612 - Polish and Other	$9,060,815	1.04	$90,608	$271,824	$86,932	$260,796

Exhibit 4-1
Breakeven Estimates for Annual Costs per Facility (adjusted to 2020$)

Industry	NAICS Code and Description	Annual Revenues per Small Entity [a]	Average Number of Facilities per Small Entity [b]	Breakeven Annual Cost per Entity: 1% Threshold [c = (1% × a)]	Breakeven Annual Cost per Entity: 3% Threshold [d = (3% × a)]	Breakeven Annual Cost per Facility: 1% Threshold [e = (1% × a)/b]	Breakeven Annual Cost per Facility: 3% Threshold [f = (3% × a)/b]
cleaning products	Sanitation Good Manufacturing						
Polymer manufacturing	325211 - Plastics Material and Resin Manufacturing	$33,570,756	1.14	$335,708	$1,007,123	$293,955	$881,864
Printing facilities where inks are used in photolithography	323111 - Commercial Printing (except Screen and Books)	$2,256,953	1.03	$22,570	$67,709	$21,930	$65,790
	325910 - Printing Ink Manufacturing	$7,404,767	1.35	$74,048	$222,143	$54,671	$164,012
Textile mills (textiles and upholstery)	313210 - Broadwoven Fabric Mills	$8,800,871	1.04	$88,009	$264,026	$84,396	$253,189
	313220 - Narrow Fabric Mills and Schiffli Machine Embroidery	$4,053,810	1.04	$40,538	$121,614	$39,164	$117,492
	313230 - Nonwoven Fabric Mills	$16,383,181	1.08	$163,832	$491,495	$151,160	$453,479
	313240 - Knit Fabric Mills	$8,001,426	1.01	$80,014	$240,043	$79,434	$238,303
	313320 - Fabric Coating Mills	$12,333,111	1.06	$123,331	$369,993	$116,573	$349,720
WWTPs	221320 - Sewage Treatment Facilities	$1,357,425	1.06	$13,574	$40,723	$12,786	$38,357

Note: Revenue values obtained from United States Census Bureau's 2017 Statistics of U.S. Businesses (SUSB). Values converted from year 2017 dollars to year 2020 dollars using the GDP Deflator.

Note: EPA did not consider the cost impacts on small government municipal drinking water utilities because they were not identified as potential major sources of PFOA and/or PFOS releases in any of the literature reviewed.

For the sector with the lowest breakeven costs per facility (Car Washes – NAICS 811192), the smallest size class reported has a revenue average of $48,496. Even in this class, the per release cost of $561 represents less than three percent of revenues and just slightly more than one percent of revenues.[90] Similarly, for five other industries,[91] the $561 cost per release is slightly more than one percent of revenues for the smallest revenue class among small entities but less than three percent (range of 1.02 percent to 1.08 percent). The annual revenues for these entities range from $51,980 to $55,256. Collectively, these entities represent less than 9 percent of the small entities reflected in Exhibit 4-1. In addition, the $561 cost is likely to overestimate the typical costs realized by these entities on an annual basis, as entities this small are unlikely to have reportable releases each year. Thus, EPA expects that there would not be a significant impact on a substantial number of small entities.

4.2.3 Resulting Impact of Proposed Rule on Small Entities

It is not clear what number of small entities in any sector would be required to report as a result of the action under consideration by EPA, but even the total per release cost of $561, when compared with the average revenues for single facilities at small entities in key sectors affected by PFAS (**Exhibit 4-1** above), does not come close to exceeding one percent of average facility level (or firm-level) small-entity revenues in any sector. As a result, this proposed action is not expected to result in a significant economic impact on a substantial number of small entities, including small government entities, under the RFA.

4.3 Impacts on Minority and Low-Income Populations: Analysis

4.3.1 Introduction

Executive Order 12898 (59 FR 7629; February 16, 1994), *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, establishes federal executive policy on environmental justice.[92] Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA defines environmental justice as the fair treatment and meaningful involvement of all people regardless of race, color, national

---

[90] Data obtained from United States Census Bureau's 2017 Statistics of U.S. Businesses (SUSB). Values converted from year 2017 dollars to year 2020 dollars using the GDP Deflator.
[91] The five other industries are Other Airport Operations (NAICS 488119); Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS 332813); Surgical and Medical Instrument Manufacturing (NAICS 339112); Fabric Coating Mills (NAICS 313320); and Sewage Treatment Facilities (NAICS 221320).
[92] https://www.epa.gov/laws-regulations/summary-executive-order-12898-federal-actions-address-environmental-justice.

origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.[93] Executive Order 14008 (86 FR 7619; January 27, 2021), *Tackling the Climate Crisis at Home and Abroad,* also calls on Agencies to make achieving environmental justice part of their missions "by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities, as well as the accompanying economic challenges of such impacts."[94] It also declares a policy "to secure environmental justice and spur economic opportunity for disadvantaged communities that have been historically marginalized and overburdened by pollution and under-investment in housing, transportation, water and wastewater infrastructure and health care."[95] EPA also released its "Technical Guidance for Assessing Environmental Justice in Regulatory Analysis" (U.S. EPA, 2016) to provide recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time and resource constraints, and analytic challenges will vary by media and circumstance.[96]

This RIA includes a screening-level analysis of the demographics of the populations in proximity to potential sites affected by the Proposed Rule and considers the possible impact of the proposed guidance on populations and locations relevant to Executive Orders 12898 and 14008.

---

[93] Fair treatment occurs when "no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies" (U.S. EPA, 2011). Meaningful involvement occurs when "1) potentially affected populations have an appropriate opportunity to participate in decisions about a proposed activity [i.e., rulemaking] that will affect their environment and/or health; 2) the population's contribution can influence [the EPA's] rulemaking decisions; 3) the concerns of all participants involved will be considered in the decision-making process; and 4) [the EPA will] seek out and facilitate the involvement of population's potentially affected by EPA's rulemaking process" (U.S. EPA, 2015). A potential EJ concern is defined as "actual or potential lack of fair treatment or meaningful involvement of minority populations, low-income populations, tribes, and indigenous peoples in the development, implementation and enforcement of environmental laws, regulations and policies" (U.S. EPA, 2015). See also https://www.epa.gov/environmentaljustice. Referenced sources are presented below:

(1) Environmental Protection Agency: Office of Environmental Justice. "Guidance on Considering Environmental Justice During the Development of Regulatory Actions". May 2015. Link: https://www.epa.gov/environmentaljustice/guidance-considering-environmental-justice-during-development-action
(2) Environmental Protection Agency: Office of Environmental Justice. "Plan EJ 2014". September 2011. Link: https://www.epa.gov/environmentaljustice/plan-ej-2014

[94] https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad.

[95] https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad.

[96] https://www.epa.gov/environmentaljustice/technical-guidance-assessing-environmental-justice-regulatory-analysis.

4.3.2 Demographic Analysis

This demographic analysis examines populations in U.S. Census block groups that intersect with identified site boundaries and designated areas around them (i.e., buffers).[97] Site spatial information can either take the form of polygons identifying the actual site boundaries, or single points designating the location (centroids), depending on the availability of data. Polygons represent the actual mapped boundary of any particular site. Centroids, on the other hand, are point estimates. To estimate the populations living near (or in some cases within) site boundaries when only centroid information is available, the analysis models centric (circular) boundaries meant to approximate site boundaries. These areas are created using certain distances around the centroid; standard distances used to approximate sites and the areas around them for RCRA and NPL site centroids are one and three miles.[98] Similarly, the analysis considers buffers of one and three miles around the site boundaries of polygons.

This proposed regulation identifies groundwater and surface water as potential sources of exposure for the identified PFAS. Because the location of future releases of PFAS is uncertain, this analysis considers populations around facilities in sectors associated with widespread historical uses and releases of PFAS as proxies for facilities that may have future releases of the PFAS considered in the proposed rule. This analysis examines the following site types as proxies for facilities that are known to have commonly used PFAS:

- Operating Department of Defense (DOD) facilities[99]
- Operating U.S. airports and airfields[100]

[97] This demographic analysis iterates the screening level method employed by EPA's OLEM to characterize the populations around sites subject to regulation and remediation under the RCRA and CERCLA statutes (as well as programs related to brownfields and underground storage tanks). OLEM is planning to refine the population apportionment method in 2022 to better capture site-specific impacts; this is not likely to affect the results of national-level screening analyses such as the one in this RIA, but will be incorporated in the final rule.
[98] https://www.epa.gov/cleanups/olem-programs-address-contamination-superfund-brownfields-and-rcra-sites-near-61-percent.
[99] Operating DOD facilities include bases, depots, training sites, camps, forts, research facilities, military airfields, etc. Dataset was acquired from: U.S. Army Corps of Engineers, "DoD Sites", June 2021. Accessed at: https://catalog.data.gov/dataset/dod-sites-boundary & https://catalog.data.gov/dataset/dod-sites-point
[100] Because the National Plan of Integrated Airport Systems (NPIAS) public facing dataset presented by the Federal Aviation Administration (FAA) does not contain geographic information, this analysis relies on data from the United Nations Office for the Coordination of Humanitarian Affairs. To assess the coverage of the UN database, this analysis cross-referenced the list of airports represented in both datasets; this exercise found that the UN data contained 98% of all airports listed in the NPIAS. Of the 2% of sites listed in the NPIAS but not in the UN database, about half were located in rural Alaska. Full citations of these datasets are presented below:
(1) United Nations Office for the Coordination of Humanitarian Affairs, "The Humanitarian Data Exchange: Airports in the United States of America", June 2021. Downloaded on June 18, 2021. Accessed at: https://data.humdata.org/dataset/ourairports-usa. The dataset categorized airports by the following size categories: small, medium, and large.

    - Large U.S. airports and airfields
    - All other U.S. airports and airfields (i.e., medium and small)
- Plastics material and resin manufacturing firms identified as having produced PFOS and/or PFOA[101,102]
- 2020 PFOS and PFOA releases reported to EPA's Toxic Release Inventory (TRI)[103]

These proxy sites may not capture actual release locations that will require reporting, and they do not reflect all sites where PFAS was used or released, but there is some consistency in the historical use across sites in these sectors. This historical use provides EPA with a reasonable starting point for examining demographic patterns. The assessment of these sites would be informed by information on the prevalence of PFOA and PFOS at these sites, the corresponding risks to local populations, and the benefits of the proposed designation. The development of reliable quantitative or even qualitative ratings of the proxy sites or sectors, however, if not feasible due to a lack of available information. There is uncertainty regarding future releases of PFOA or PFOS and the risks associated with future releases would depend on site-specific information that is not readily available, such as the likely size of a release at a given site and the exposure level for each site if a release were to occur.

Exhibit 4-2 summarizes several key demographics of the total populations near the universe of proxy sites and compares these demographics to U.S. national averages. The six key demographic categories examined are minority (reflecting an examination of both race and ethnicity; minority is defined as populations excluding non-Hispanic White), poverty level, linguistic isolation, education, age (specifically population less than five years old and greater than 64 years old), and age of housing.

---

(2) Federal Aviation Administration. "National Plan of Integrated Airport Systems (NPIAS) - Current – Airports", October 07, 2020. Downloaded February 2022. Accessed at: https://www.faa.gov/airports/planning_capacity/npias/current/

[101] Data acquired from: Environmental Protection Agency, "Enforcement and Compliance History Online (ECHO)", August 2021.

[102] Because not all plastic material and resin manufacturers use PFAS, only a fraction of the facilities reported in ECHO as plastics material and resin manufacturers were used in this analysis. To filter facilities involved in the use or manufacture of PFAS, this RIA drops all facilities that are not owned by the following companies: 3M, Dupont, Chemours, Arkema, Asahi, BASF, Clariant, Daikin, or Solvay Solexis. All companies, except Chemours, were listed by EPA as participants in the PFOA Stewardship Program. Chemours, a spin-off of Dupont, is a known manufacturer of PFAS products and is listed in a lawsuit filed by the State of Michigan. Sources: (1) Environmental Protection Agency, "Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA", 2021. Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas (2) Michigan Department of Environment, Great Lakes, and Energy, "Michigan Files Lawsuit Against 3M, DuPont and others for PFAS Contamination", 2020. Link: https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-517280--,00.html.

[103] Environmental Protection Agency, "Envirofacts: TRI Search", July 2021. Accessed at: https://www.epa.gov/enviro/tri-search.

Exhibit 4-2
Proportions of Key Demographics in the Total Near Site Population and the Total U.S. Population

Demographic Category	Population within 1 or 3 miles of a Plastics Material and Resin Manufacturer and/or a Release Reported to TRI		Population within 1 or 3 miles of a DOD site		Population within 1 or 3 miles of a Large Airport		Population within 1 or 3 miles of a Small or Medium Airport		U.S. Population
	1 mile	3 miles	1 mile	3 miles	1 mile	3 miles	1 mile	3 miles	
Race									
Asian	6.02%	6.82%	7.93%	7.42%	6.22%	8.16%	3.73%	4.34%	5.39%
Black/African American	22.58%	23.56%	15.83%	16.34%	14.51%	17.03%	9.04%	10.26%	12.65%
Hawaiian/Pacific Islander	0.06%	0.08%	1.07%	0.55%	0.36%	0.33%	0.19%	0.19%	0.18%
Native American	0.44%	0.36%	0.78%	0.75%	0.71%	0.74%	0.91%	0.84%	0.83%
Other	7.80%	7.76%	10.94%	10.73%	11.65%	12.90%	7.23%	7.65%	8.26%
Minority									
Minority	48.49%	48.91%	50.94%	50.63%	48.71%	56.70%	32.11%	34.71%	39.56%
Ethnicity									
Hispanic (any race)	17.31%	16.06%	21.77%	22.98%	24.38%	28.39%	16.13%	16.97%	18.65%
Poverty Level									
Households below the poverty level	18.76%	16.65%	13.80%	14.61%	13.56%	15.31%	12.17%	13.01%	13.70%
Households with a ratio of income to poverty level of two and below	39.95%	36.70%	34.37%	34.58%	62.68%	62.34%	30.73%	31.82%	32.34%
Other Demographics									
Linguistically isolated households	4.17%	4.44%	5.32%	6.34%	6.51%	9.16%	3.10%	3.61%	5.08%
Less than a High School Education	9.55%	8.97%	7.58%	8.59%	8.82%	10.76%	8.11%	8.13%	8.44%
Under 5 years of age	6.25%	6.26%	7.20%	6.78%	7.30%	6.82%	6.26%	6.26%	6.13%
Over 64 years of age	12.98%	13.73%	12.08%	13.21%	11.04%	12.55%	15.55%	15.23%	15.29%
Structures Built Pre-1960	53.59%	48.48%	25.71%	29.73%	28.13%	34.50%	21.64%	24.78%	28.01%
Total U.S. Population Captured in Proximity									
% of U.S. Population Captured in Proximity	0.15%	1.42%	2.55%	10.08%	0.12%	2.83%	2.57%	23.87%	100%

This initial, high-level assessment suggests that populations within one or three miles of these sites vary based on site type:

- **Plastics material and resin manufacturers and/or releases reported to TRI** - the average population within one or three miles of a plastics material and resin manufacturer and/or a release reported to TRI has higher rates of households experiencing poverty, older housing stocks, and larger percentages of minority residents than the U.S. averages for these demographics. Specifically, a much higher percentage of Black residents live near plastic material and resin manufacturers reporting to the TRI. The remaining variables are generally similar to (i.e., within +/- 10 percent of) U.S. average populations.
- **Operating DOD facilities** - the average population within one or three miles of a DOD site has larger percentages of minority residents than the U.S. average, driven in large part by a notably higher percentage of Black residents. Populations near DOD sites are within +/- five percent of the U.S. average in all other metrics.
- **Airports and airfields –** Because airports across the country vary widely in size, this analysis categorizes them into three general size classes: small, medium, and large. For presentation purposes, this analysis presents large airports separately and groups the remaining two size categories, small and medium. The average population within one or three miles of a small or medium airport is similar to the U.S. average for all demographic variables, reflecting the larger number and geographic distribution of these types of airports and airfields in the U.S. In contrast, populations within one or three miles of a large airport have higher rates of households experiencing poverty and larger percentages of minority residents. The remaining variables are generally similar to (i.e., within +/- 10 percent of) U.S. average populations.

These findings, combined with the uncertainty surrounding the location of future releases, are indicative of potential impacts but do not provide a clear indication of the type of disparities related to potential exposure to PFAS. Consistent with the priorities outlined in Executive Orders 12898 and 14008, it is unclear whether the proposed regulation will have a significant impact on disadvantaged populations or communities with environmental justice (EJ) concerns relative to other communities. While the locations of reporting releases are unknown, to the extent that these proxy locations are representative of likely reporting locations, this screening analysis suggests that the reporting required under the rule may provide better information to nearby populations potentially at risk of exposure, including communities with EJ concerns. To the extent that PFAS releases are consistent with the broader releases reported to TRI and typically involve disposal or manufacturing sites, demographic data around plastics material and resin manufacturer sites and historical releases may be a more reliable predictor of the type of community potentially affected by this proposed rulemaking. Specific site conditions and demographic patterns may become clear as reporting occurs following completion of a final rule.

Although the impact of the findings in this analysis are unclear, published literature supports the conclusion that PFAS reporting can help minority and low-income populations. For instance, reported data from Northeastern University's Social Science Environmental Health Institute published in 2019 show that minority and low-income populations are disproportionately exposed to PFAS as nearly 39,000 more low-income households (15% more than the expected based on U.S. census data) and approximately 295,000 more people of color (22% more than expected) live within 5 miles of a site contaminated with PFAS.[104] In addition, information on the broader links between PFAS exposure and communities with EJ concerns continues to emerge. An August 2021 report the Natural Resources Defense Council examined exposure to PFAS in drinking water in California and found that at least 69 percent of state-identified disadvantaged communities have PFAS contamination in their public water systems, and a number of these communities have levels of PFAS contamination that are higher than average.[105]

As research continues to expand understanding about the distribution of PFAS impacts, it is important to note that this proposed regulation will result in more information about the location and extent of releases. This improved information will not increase exposure risk for communities with EJ concerns and may improve the speed and design of remediation. Because detection of PFAS contamination in drinking water is linked to the location of industrial facilities handling these chemicals, incentivizing the prevention of releases could benefit communities with EJ concerns near these facilities.[106] EPA is committed to minimizing and/or eliminating existing barriers and burdens that communities with environmental concerns may encounter related to accessing data and information collected as a result of this rulemaking, if finalized. EPA seeks comment on strategies to improve access to the reporting data expected to be collected, if designation of PFOA and PFOS as hazardous substances is finalized, for communities with environmental justice concerns.

4.3.3 Analytic Limitations

The following methodological assumptions and limitations affect the demographic analysis:

---

[104] Northeastern University - The PFAS Project Lab, "PFAS Contamination Is an Equity Issue, and President Trump's EPA Is Failing to Fix It" October 31, 2019. Available at: https://pfasproject.com/2019/10/31/pfas-contamination-is-an-equity-issue-and-president-trumps-epa-is-failing-to-fix-it/

[105] Lee, Susan, Avinash Kar, and Dr. Anna Reade, *Dirty Water: Toxic "Forever" PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities*. Natural Resources Defense Counsel, New York. 2021.

[106] Hu, Xindi C.,,David Q. Andrews, Andrew B. Lindstrom, Thomas A. Bruton, Laurel A. Schaider, Philippe Grandjean, Rainer Lohmann, Courtney C. Carignan, Arlene Blum, Simona A. Balan, Christopher P. Higgins, and Elsie M. Sunderland. Environmental Science & Technology Letters. 2016. "Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants".
Note, this study uses 16 industrial sites listed in EPA's 2010/2015 PFOA Stewardship to proxy the location of industrial sites handling PFAS.

- Due to data limitations regarding the current manufacture and uses of PFAS, this analysis cannot predict where exposures and releases of PFAS are likely to occur. Instead, this analysis uses operating DOD facilities, plastics material and resin manufacturers, releases reported to TRI, and operating airports and airfields (locations with demonstrated historical use of PFAS) to proxy areas with potential PFAS exposures and releases. However, these areas may not reflect actual release locations that would require reporting, and the buffers identified represent only an approximation of the potential risk of exposure to PFAS.[107] Actual exposure patterns at specific sites could be highly local, variable, or extend past the three-mile buffers (e.g., in water systems).
- The goal of this analysis is to examine the potential demographic impacts of highly local release and exposure patterns of PFOS and PFOA. Because of U.S. Census data limitations, this analysis pulls demographic data across entire census block groups and may not accurately specific populations affected by a release where those populations vary within block groups.
- Because PFAS exposure through drinking water is understood to be an important route of exposure where sources of drinking water are contaminated, an analysis of drinking water sources and their vulnerability to PFAS contamination would be important to understand potential risks for areas with releases. However, because future release locations are not known, this analysis would not provide additional insight at this time.
- For sites without polygon data, this analysis relies on the use of centroids and one-mile and three-mile centric buffers to replicate site location and surface area, identifying the affected population as the entire population of any U.S. Census block group that falls within the buffer. Many sites in this universe have irregular site areas that do not align with a centroid-based model, and the shape and size of Census block groups varies with population density. This means that this analysis may not capture the specific populations around each site with accuracy, though patterns across a number of sites are likely robust. Specifically, this approach may undercount populations located near sites that are large and/or located in rural areas, where the area of each Census block group is large and centroids are less likely to fall within the buffer.[108]

[107] While airports may not currently store or use quantities of PFOA or PFOS equal to or above one pound pursuant to CERCLA section 102 (or quantities sufficient to trigger release notification requirements for mixtures under CERCLA Section 103), this analysis notes them as known sites with past use of PFOA and PFOS and a broad geographic distribution. It is not clear what, if any, reporting obligations may be required by airports as a result of this rule.

[108] There is an ongoing effort to rectify these limitations by deploying a more granular population apportionment method that more accurately captures within-block-group variation. Methods under review include aligning OLEM's demographic analysis methodology with the methodology used by EPA's EJSCREEN, as well as other emerging tools (e.g., emerging recommendations from the White House Council on Environmental Quality). However, this will not be completed until at least early 2022.

4.3.4 Supplementary and Sensitivity Analyses

To measure the effectiveness of centroids in characterizing sites that could potentially release PFAS, this RIA examines demographic characteristics for specific sites using EPA's EJSCREEN to validate and expand results to larger areas around sites to better capture populations in rural or other low-density areas (**Exhibit 4-4**). Of the 15,816 sites examined in the analysis, 4,543 (or 29 percent) did not intersect with a census block group centroid within the three-mile buffer, resulting in a population count of "0" affected. As shown in **Exhibit 4-3,** the majority of airports that do not intersect with a census block group are characterized as "small".[109] As a result, demographic information around these sites was not factored into average calculations presented in **Exhibit 4-2**. However, the vast majority of these sites are small airports, which overall are consistent with U.S. average population demographics. The centroid methodology created few empty data points for operating DOD facilities (52), plastics material and resin manufacturers (3), and TRI releases (0). Like **Exhibit 4-2**, **Exhibit 4-3** illustrates the variability of demographic data across site type. On average, airports across the U.S. are surrounded by populations that reflect national averages in relevant demographic categories. Large airports, however, are more likely to be surrounded by minority and low-income populations than medium or small airports. Some DOD sites are surrounded by populations with higher concentrations of minority and low-income residents, but the majority of these sites are below the national averages for these metrics. In contrast, areas around plastics material and resin manufacturer sites and/or sites reporting releases to TRI, on average, are in areas with higher concentrations of minority residents and households experiencing poverty than the U.S. averages for these demographics, suggesting that releases related to manufacturing facilities could have environmental justice implications.

Exhibit 4-3
Demographics by Site and Site Type

Site Type	Site Count	Do not intersect a Census Block at 3 miles		Minority Population above the National Average at 3 miles		Poverty Level (Households) above the National Average at 3 miles	
		# of Sites	% of Total Site Type	# of Sites	% of Total Site Type	# of Sites	% of Total Site Type
Airport and Airfields	14,948	4,488	30%	1,833	12%	4,014	27%
Large	188	1	1%	101	53%	81	43%
Medium	678	116	17%	212	31%	277	41%
Small	14,082	4,370	31%	1,520	11%	3,656	26%
DOD Facilities	762	52	7%	312	41%	329	43%
Plastics Material and Resin Manufacturers	98	3	3%	46	47%	50	51%
TRI Historical Releases	7	0	0%	4	56%	5	71%
Total	**15,816**	**4,543**	**29%**	**2,195**	**14%**	**4,398**	**28%**

[109] The only "large" airport (Lake Havasu City Airport) that does not intersect a census block at 3 miles is in a very rural area. According to EJ Screen, only 2,971 people live within 3 miles, of which 221 (or 7%) are people of color.

As an additional check, this RIA examines four- and five-mile buffers around the 2020 PFOS and PFOA releases reported to TRI using EPA's EJSCREEN tool. In **Exhibit 4-4**, these results are presented next to the results of the one- and three-mile buffers calculated for this RIA.[110] For these nine sites, the one-mile buffer does not capture populations at three sites, including Cottage Grove, which reported to TRI that PFAS was released for disposal. This information suggests that the one-mile buffer may not accurately capture representative demographic data in surrounding communities for some key sites, such as large manufacturing facilities. The three-mile buffer appears to capture demographics for the community with more accuracy. With the exception of Clean Harbors El Dorado LLC, minority demographics minimally change as site buffers are expanded, confirming that the screening method is generally robust but should not be used for detailed site-specific characterizations. A site-by-site breakdown also presents a more complicated relationship between minority populations and potential PFAS release locations; the standard deviation for minority population around potential release sites is large. Generally, communities around these sites either have large or small minority populations, although most sites have above average minority populations, but more site-specific analysis would be required to fully characterize specific populations. Absent certainty about the locations of future releases, this analysis provides a general indication that releases related to manufacturing sites, in particular, as well as some active military sites, may have implications for communities with environmental justice (EJ) concerns.

Exhibit 4-4
Centroids Modeled Around TRI Release Sites

Name	1-mile		3-mile		4-mile		5-mile	
	Population	Minority	Population	Minority	Population	Minority	Population	Minority
3M Cottage Grove	0	0%	17,011	19%	30,066	16%	50,198	15%
BASF CORP - Freeport Site	1,199	67%	23,526	59%	38,980	56%	56,440	54%
Clean Harbors Deer Park LLC	8,589	89%	68,467	92%	159,187	92%	275,545	91%
Clean Harbors El Dorado LLC	1,565	77%	11,618	70%	19,042	53%	21,007	51%
Clean Water Environmental LLC	3,782	66%	21,654	83%	45,707	83%	77,325	78%
Heritage Thermal Services	4,130	12%	18,317	10%	24,474	7%	32,046	8%

[110] For release quantities associated with these sites, please refer to Exhibit 3-2. Of the nine TRI releases, the following sites experienced a release of either PFOS, PFOA, or both above a pound: 3M Cottage Grove Center, Clean Harbors El Dorado, Vickery Environmental Inc., BASF Corp - Freeport Site, TM Deer Park Services, Wayne Disposal Inc., and Clean Water Environmental LLC. Based on the demographic data in Exhibit 4-4, the following sites experienced a substantial release around communities with EJ concerns: BASF Corp – Freeport Site, Clean Harbors El Dorado LLC, Clean Water Environmental LLC, and TM Deer Park Services LP.

Exhibit 4-4 Centroids Modeled Around TRI Release Sites								
TM Deer Park Services LP	0	0%	6337	56%	24,665	55%	63,321	55%
Vickery Environmental Inc	0	0%	1,949	8%	3,088	8%	9,162	9%
Wayne Disposal Inc	6,979	42%	28,971	36%	41,545	34%	63,571	35%
National Average (TRI Releases)	26,244	59%	197,850	62%	386,754	65%	648,615	65%

4.4 Impacts on Children's Health Analysis

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA's *2021 Policy on Children's Health* (October 5, 2021)[111] requires EPA to consider early life exposures and lifelong health consistently and explicitly in all human health decisions. EPA believes that the environmental health or safety risk posed by exposure to PFOA and/or PFOS may have a disproportionate effect on children. Thus, indirect benefits resulting from speedier identification, assessment, and response activities addressing PFOA and PFOS exposures are expected to reduce the associated health effects on nearby populations, including children. To the extent that the proposed designation reduces the risks of these adverse health effects, this will lead to a health care cost savings and a reduction of health risks to children. Discussions of health and risk assessments related to PFOA and PFOS, including developmental and reproductive health effects, are contained in EPA's Health Effects Support Documents for PFOA and PFOS (2016).

4.5 Regulatory Planning and Review

Under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), EPA, in conjunction with the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA), must determine whether a regulatory action is "significant" and therefore subject to OMB review and the full requirements of the Executive

[111] https://www.epa.gov/system/files/documents/2021-10/2021-policy-on-childrens-health.pdf.

Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, the Agency has determined that this action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. The action may raise novel legal or policy issues arising out of legal mandates, the Presidents' priorities, or the principles set forth in the EO. Additionally, while EPA is not considering costs in its hazardous substance designation decisions in this proposed rule, and despite that there is still significant uncertainty and lack of data as discussed in the economic analysis, OMB designated this proposed rulemaking as an economically significant action pursuant to E.O. 12866. Any changes made in response to the OMB recommendations have been documented in the docket. Findings of the regulatory cost analysis (**Chapter 3**) indicate that the rule, as proposed, is projected to result in aggregate annual social direct costs of approximately $0 under the lower bound scenario, and approximately $0.37 million under the upper bound scenario.

4.6 Unfunded Mandates Analysis

Signed into law on March 22, 1995, the Unfunded Mandates Reform Act (UMRA) calls on all federal agencies to provide a statement supporting the need to issue any regulation containing an unfunded federal mandate and describing prior consultation with representatives of affected State, local, and tribal governments.

The proposed rule is subject to the requirements of sections 202 and 205 of UMRA. In general, a rule is subject to the requirements of these sections if it contains "Federal mandates" that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. To the extent that state, local, or tribal governments are required to report releases under the proposed rule, it represents an unfunded mandate. However, this proposed action is not expected to impose an unfunded mandate of $100

million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small government entities as analyzed in Section 4.2 above.

4.7 Federalism Analysis

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." EPA typically considers a policy to have federalism implications if it results in the expenditure by State and/or local governments in the aggregate of $25 million or more in any one year.

Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation.

This action does not have federalism implications as it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

4.8 Tribal Government Analysis

Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications."

This proposed action does not have tribal implications as specified in Executive Order 13175. Because the proposed rule is expected to result in minimal costs, EPA does not expect that it would result in any costs or adverse impacts on tribal entities. Thus, Executive Order 13175 does not apply to this rule.

4.9 Employment Impacts

The employment impacts of this action are likely to be minimal and include additional hours for the National Response Center (NRC), State Emergency Response Commissions (SERCs) (or TERCs), and Local Emergency Planning Committees (LEPCs) (or TEPCs) employees who answer the phones and record information regarding releases and those NRC, SERCs (or

TERCs), and LEPCs (or TEPCs) employees who input that data into the database. The reporting facilities will require employees to spend time making a release report. However, the per facility release costs associated with PFOA or PFOS above the RQ of 1 lb per 24 hours are estimated to be approximately $561. This low cost is not expected to affect the demand for labor at regulated facilities.

Note, there may be some employment impacts resulting from federal property transfers. As described in **Section 3.4**, it is difficult to estimate the potential cost or impact resulting from these requirements.

SOURCES CITED

California Air Resources Board, "Chemical Fume Suppressants Approved for Use at Specific Surface Tensions," September 6, 2016. Available: https://www.arb.ca.gov/toxics/chrome/fumesuppresslistfinal9.6.16.pdf

California Water Boards, "Water Boards PFAS Phased Investigation Approach," March 6, 2019. Available: https://www.waterboards.ca.gov/pfas/docs/7_investigation_plan.pdf

Campbell, Katherine, Stephan E. Sefcik, and Naomi S. Soderstrom (1998), "Site uncertainty, allocation uncertainty, and superfund liability valuation," Journal of Accounting and Public Policy, Vol. 17 (1998): 331-366.

DHL. 2021. DHL eCommerce Solutions: Limited Quantity Policy. DHL. Accessed online Sept. 2021: https://www.dhl.com/content/dam/dhl/local/us/dhl-ecommerce/documents/pdf/us-ecommerce-limitied-quantity-transportation-policy.pdf

Environmental Protection Agency. "542-R-19-002: 2019 Remediation Market Study". January 15, 2020.

Environmental Protection Agency, "Basic Information for Chemical Data Reporting," August 29, 2016. Available: https://www.epa.gov/chemical-data-reporting/basic-information-chemical-data-reporting

Environmental Protection Agency, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances. U.S. Environmental Protection Agency. 2022. Docket ID No. EPA-HQ-OLEM-2019-0341. https://www.regulations.gov

Environmental Protection Agency, "Enforcement and Compliance History Online (ECHO)", August 2021.

Environmental Protection Agency, "Envirofacts: TRI Search", July 2021. Accessed at: https://www.epa.gov/enviro/tri-search

Environmental Protection Agency. Certain perfluoroalkyl sulfonates. U.S. Environmental Protection Agency. Code of Federal Regulations. 40 CFR 721.9582. 2014. https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-sec721-9582.pdf

Environmental Protection Agency. Fact Sheet: 2010/2015 PFOA Stewardship Program.:Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program

Environmental Protection Agency. Information Collection Request (ICR) No. 1049.14: Renewal of Information Collection Request for the Episodic Releases of Oil and Hazardous Substances. OMB Control No. 2050-0046, June 2018.

Environmental Protection Agency. Information Collection Request (ICR) No. 1395.10: Statement Supporting the Renewal of the Information Collection Procedure for Emergency Planning and Release Notification Requirements. OMB Control No. 2050-0092. April 2019.

Environmental Protection Agency. Regulatory Impact Analysis: Final Rulemaking for 2017-2025 Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards, EPA-420-R-12-016, August 2012.

Environmental Protection Agency: Office of Environmental Justice. "Guidance on Considering Environmental Justice During the Development of Regulatory Actions". May 2015. Link: https://www.epa.gov/environmentaljustice/guidance-considering-environmental-justice-during-development-action

Environmental Protection Agency: Office of Environmental Justice. "Plan EJ 2014". September 2011. Link: https://www.epa.gov/environmentaljustice/plan-ej-2014

Environmental Protection Agency, "Per- and Polyfluoroalkyl Substances (PFAS): Incineration to Manage PFAS Waste Streams", July 2019. Available at: https://www.epa.gov/sites/default/files/2019-09/documents/technical_brief_pfas_incineration_ioaa_approved_final_july_2019.pdf

Environmental Protection Agency, "Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA", 2021. Link: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas

Environmental Protection Agency. "Superfund Enterprise Management System (SEMS). February 2022.

Environmental Protection Agency (U.S. EPA). Technical Fact Sheet -- Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA). 2017. Accessed online Sept. 2021: https://www.epa.gov/sites/default/files/2017-12/documents/ffrrofactsheet_contaminants_pfos_pfoa_11-20-17_508_0.pdf

Department of Defense: Office of the Under Secretary of Defense for Acquisition and Sustainment. "Per-and Polyfluoroalkyl Substances Cleanup Costs". July 2021.

Federal Aviation Administration. "National Plan of Integrated Airport Systems (NPIAS) - Current – Airports", October 07, 2020. Downloaded February 2022. Accessed at: https://www.faa.gov/airports/planning_capacity/npias/current/

Federal Register. Environmental Protection Agency, 40 CFR Part 721 - Perfluoroalkyl Sulfonates; Significant New Use Rule, December 9, 2002. Accessed online December 2021: https://www.govinfo.gov/content/pkg/FR-2002-12-09/pdf/02-31011.pdf

Federal Register. Environmental Protection Agency, 40 CFR Part 721 - Perfluoroalkyl Sulfonates; Significant New Use Rule, March 11, 2002. Accessed online December 2021: https://www.govinfo.gov/content/pkg/FR-2002-12-09/pdf/02-31011.pdf

FedEx. 2021. Service Guide. Fedex. Accessed online September 2021: https://www.fedex.com/content/dam/fedex/us-united-states/services/Service_Guide_2021.pdf

Genualdi, Susan; Lowri deJager; and Timothy Begley. Center for Food Safety and Applied Nutrition, Food and Drug Administration. 2019. "Investigation of Per- and Polyfluoroalkyl Substances (PFAS) in U.S. food products", Presentation at the 29th annual European meeting of the Society of Environmental Toxicology and Chemistry

Glüge, J; Scheringer, M; Cousins, IT; DeWitt, JC; Goldenman, G; Herzke, D; Lohmann, R; Ng, CA; Trier, X; Wang, Z. (2020). An overview of the uses of per-and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts 22: 2345-2373. https://www.ncbi.nlm.nih.gov/pubmed/33125022

Graff Zivin, Joshua and Matthew Neidell. (2018). "Air pollution's hidden impacts: Exposure can affect labor productivity and human capital," *Science*. Vol. 359, Issue 6371.

Graff Zivin, Joshua and Matthew Neidell. (2013). "Environment, Health, and Human Capital," NBER Working Paper 18935, April 2013; and

Graff Zivin, Joshua and Matthew Neidell. (2012). "The impact of Pollution on Worker Productivity," *American Economic Review*. Vol. 102(7): 3652-3673.

Hogue, Cheryl. "Governments Endorse Global PFOA Ban, With Some Exemptions," Chemical & Engineering News, May 6, 2019. Available: https://cen.acs.org/environment/persistent-pollutants/Governments-endorse-global-PFOA-ban/97/web/2019/05

Hogue, Cheryl. "Impacts of Used PFAS into U.S. Scrutinized," Chemical & Engineering News, March 3, 2019. Available: https://cen.acs.org/environment/persistent-pollutants/Imports-used-PFAS-US-scrutinized/97/i9

Hu, Xindi C.,,David Q. Andrews, Andrew B. Lindstrom, Thomas A. Bruton, Laurel A. Schaider, Philippe Grandjean, Rainer Lohmann, Courtney C. Carignan, Arlene Blum, Simona A. Balan, Christopher P. Higgins, and Elsie M. Sunderland. Environmental Science & Technology Letters. 2016. "Detection of Poly- and Perfluoroalkyl Substances (PFASs) in

U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants".

ICF. 1985. Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act. Volume 1: A Report to the Oil and Hazardous Materials Spills Branch Office of Research and Development and Environmental Response Division, Office of Emergency and Remedial Response, U.S. EPA. EPA Contract 68-03-03182

Interstate Technology and Regulatory Council, "12 Treatment Technologies". August 2021. Available at: https://pfas-1.itrcweb.org/12-treatment-technologies/#12_3 .

Interstate Technology and Regulatory Council, "PFAS Fact Sheets," 2018. Available: https://pfas-1.itrcweb.org/fact-sheets/

Interstate Technology and Regulatory Council, "Regulations, Guidance, and Advisories for Per- and Polyfluoroalkyl Substances (PFAS)," January 2018. Available: https://pfas-1.itrcweb.org/wp-content/uploads/2018/01/pfas_fact_sheet_regulations__1_4_18.pdf

Interstate Technology and Regulatory Council, "History and Use of Per- and Polyfluoroalkyl Substances (PFAS)". April 2020. Available at: https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_History_and_Use_April2020.pdf

Khanna, Madhu, Wilma Rose H. Quimio, and Dora Bojilova. (1998). "Toxics Release Information: A Policy Tool for Environmental Protection," Journal of Environmental Economics and Management, Vol. 36(3): 243-266.

Konar, Shameek and Mark A. Cohen. (1997), "Information As Regulation: the Effect of Community right to Know Laws on Toxic Emissions," Journal of Environmental Economics and Management, Vol. 32, pp. 109-124.

Konar, Shameek and Mark A. Cohen. (2000). "Why do Firms Pollute (and Reduce) Toxics Emissions?", unpublished working paper, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=922491 .

Lee, Susan, Avinash Kar, and Dr. Anna Reade, "Dirty Water: Toxic "Forever" PFAS Chemicals are Prevalent in the Drinking Water of Environmental Justice Communities." Natural Resources Defense Council, New York. 2021

Memorandum from Barry Breen, Director, Office of Site Remediation Enforcement, US EPA (Sep. 30, 1997) (General Policy on Superfund Ability to Pay Determinations).

Memorandum from Susan Shinkman, Director, Office of Civil Enforcement, and Cynthia Mackey, Director, Office of Site Remediation Enforcement, US EPA (June 29, 2015)

(Guidance on Evaluating a Violator's Ability to Pay a Civil Penalty in an Administrative Enforcement Action)

Michigan Department of Environment, Great Lakes, and Energy, "Michigan Files Lawsuit Against 3M, DuPont and others for PFAS Contamination", 2020. Link: https://www.michigan.gov/pfasresponse/0,9038,7-365-86513_96296-517280--,00.html

Michigan PFAS Action Response Team, "Firefighting Foam and PFAS," https://www.michigan.gov/pfasresponse/investigations/firefighting-foam , 2022.

Nadia Kounang, "FDA Confirms PFAS Chemicals are in the U.S. Food Supply," CNN. June 3, 2019. Available: https://www.cnn.com/2019/06/03/health/pfas-food-supply-fda/index.html

New York Department of Environmental Conservation, "PFOS/PFOA Facility Identification Survey", 2017. Link: https://www.dec.ny.gov/docs/remediation_hudson_pdf/pfoasurvey1.pdf

Northeastern University Social Science Environmental Health Research Institute, "Fayetteville Works Plant," 2019. Available: https://pfasproject.com/fayetteville-north-carolina/

Northeastern University - The PFAS Project Lab, "PFAS Contamination Is an Equity Issue, and President Trump's EPA Is Failing to Fix It" October 31, 2019. Available at: https://pfasproject.com/2019/10/31/pfas-contamination-is-an-equity-issue-and-president-trumps-epa-is-failing-to-fix-it/

Probst, Katherine N. (2020). "Superfund at 40: Unfulfilled Expectations", in Looking Back to Move Forward: Resolving Health & Environmental Outcomes, edited by Hampden T. Macbeth. State Energy & Environmental Impact Center, New York University Law School.

Renner, R., 2006. The long and the short of perfluorinated replacements. Environ. Sci. Technol., 12e13.

Schultz, Melissa M., Christopher P. Higgins, Carin A. Huset, Richard G. Luthy, Douglas F. Barofsky, and Jennifer A. Field. Environmental science & technology. 2006. "Fluorochemical mass flows in a municipal wastewater treatment facility.", 7350-7357.

State of Washington Department of Ecology, "Toxics in Firefighting Law." https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/PFAS/Toxics-in-firefighting

Stockholm Convention, "Guidance for the inventory of perfluorooctane sulfonic acid (PFOS) and related chemicals listed under the Stockholm Convention on Persistent Organic Pollutants," March 31, 2014. Available:

http://chm.pops.int/Implementation/NIPs/Guidance/GuidancefortheinventoryofPFOS/tabid/3169/Default.aspx

Susan Genualdi, Lowri deJager, and Timothy Begley. Center for Food Safety and Applied Nutrition, Food and Drug Administration. 2019. "Investigation of Per- and Polyfluoroalkyl Substances (PFAS) in U.S. food products", Presentation at the 29th annual European meeting of the Society of Environmental Toxicology and Chemistry.

Toxics Use Reduction Institute, "Per- and Poly-fluoroalkyl Substances (PFAS): Policy Analysis," May 2021. Available: https://www.mass.gov/doc/turi-pfas-policy-analysis-may-2021/download

U.S. Army Corps of Engineers, "DoD Sites", June 2021. Accessed at: https://catalog.data.gov/dataset/dod-sites-boundary & https://catalog.data.gov/dataset/dod-sites-point

United Nations Office for the Coordination of Humanitarian Affairs, "The Humanitarian Data Exchange: Airports in the United States of America", June 2021. Downloaded on June 18, 2021. Accessed at: https://data.humdata.org/dataset/ourairports-usa

United States Postal Service (USPS). 2021. HAZMAT Shipping Tutorial. Accessed online Sept. 2021: https://www.uspsdelivers.com/hazmat-shipping-safety/#step-4-1

UPS. 2021. 49 CFR Shipping Examples. UPS. Accessed online 2021: https://www.ups.com/us/en/help-center/packaging-and-supplies/special-care-shipments/hazardous-materials/49-cfr-examples.page?

U.S. Department of Health & Human Services, "Per- and Polyfluoroalkyl Substances (PFAS) and Your Health," January 10, 2018. Available: https://www.atsdr.cdc.gov/pfas/health-effects.html

United States Government Accountability Office (GAO). "Report GAO-21-421: Report to Congressional Committees - DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information". June 2021.

U.S. National Response Team, "Regional Response Teams," February 2019. Available: https://www.nrt.org/sites/2/files/RRT_Factsheet_02142019%20final.pdf.

Winchell, Lloyd J.; John J. Ross; Martha J.M. Wells; Xavier Fonoll; John W. Norton, Jr; and Katherine Y. Bell. "Per- and polyfluoroalkyl substances thermal destruction at water resource recovery facilities: A state of the science review", June 2021. Water Environ Res, Vol. 93(6): 826-843.

UNITED NATIONS

UNEP

SC

UNEP/POPS/POPRC.14/6/Add.2

Distr.: General
8 October 2018

Original: English

Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Fourteenth meeting
Rome, 17–21 September 2018

Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting

Addendum

Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

Note by the Secretariat

At its fourteenth meeting, by its decision POPRC-14/2, the Committee adopted an addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds on the basis of the draft contained in the note by the Secretariat (UNEP/POPS/POPRC.14/3), as revised during the meeting. The text of the addendum to the risk management evaluation as adopted is set out in the annex to the present addendum. It has not been formally edited.

K1802750 281118

Norway estimated that the costs of remediation of airport land contaminated with PFOS would be in the range of 4-40 million dollars per airport (Norway, 2018a).

232. Cousins (2016) (quoted within IPEN (2018)) further highlighted that the costs of cleaning up the contaminated site is only one of many costs associated with the legacy contamination from PFAS-containing fire-fighting foams (both long and short chain); Others include cost of analytical monitoring of PFAS, destruction of old stockpiles,
clean-up of equipment contaminated by previous use, costs of developing and commercializing sustainable alternatives, funding new research, health costs, legal costs, etc. Most of these costs will be borne by taxpayers, as it is challenging and often costly to identify the principal responsible party or parties in practice. However, in environmental law many countries have adopted the "polluter pays principle" to make the party responsible for the pollution responsible for cleaning it up. It is regarded as a regional custom because of the strong support it has received in most OECD countries and in the EU as well as in Norway. It is also a fundamental principle in US environmental law (Norway, 2018).

233. PFOS and PFOA containing foams have been used until recently in developing countries even with recent imports. Sites where PFOS and likely PFOA containing foams have been used for fire-fighting practice or sites of fire events are likely contaminated (Suriname 2017). Although such sites include areas of drinking water reservoirs, they are often not investigated due to the lack of monitoring capacity and available funding.

234. Recognizing the serious public health implications associated with contamination of drinking water sources by PFAS fire-fighting foams and the need to prevent further harm, policymakers in Washington State (USA)[62] recently enacted the first state legislation in the USA that prohibits the use of PFAS-containing fire-fighting foams for training purposes beginning on July 1, 2018 and prohibits the sale of PFAS-containing fire-fighting foams for use in Washington State beginning on July 1, 2020. Furthermore, Land et al. (2018) comment on temporal trends of perfluoroalkyl acids in humans and in the environment, stating: "In regions where regulations and phase-outs have been implemented, human concentrations of PFOS, PFDS, and PFOA are generally declining, while previously increasing concentrations of PFHxS have begun to level off".

235. The Swedish Chemicals Agency estimates the costs related to PFAS contamination of drinking water for two case examples amounting to 1 million € per year for charcoal filtering of water in Uppsala and to 3 million € for new water supply in Ronneby, which is a small city where approximately 5000 households were immediately affected when high levels of PFASs were discovered in 2013 (Swedish Chemicals Agency, 2016).

236. Patrick Breysse,[63] Director of the US Centers for Disease Control's National Center for Environmental Health, described the contamination of drinking water by perfluorinated chemicals in AFFF as "one of the most seminal public health challenges for the next decades." Unlike other persistent, bioaccumulative toxic chemicals such as PCBs and dioxins, PFAS are highly water soluble and do not break down in the environment. Of particular concern, perfluoroalkyl acids that reach groundwater "may remain there indefinitely, impacting drinking water sources for generations to come." In the United States alone, the drinking water of more than six million people in many communities throughout the country has been found to contain highly fluorinated chemicals at concentrations of concern. Cousins (2016) recommend a precautionary approach that respects the "design for degradation" principle of Green Chemistry, stating that "according to this reasoning, society should replace all PFAS-based fire-fighting foams with non-persistent fire-fighting products, given that they can lead to poorly reversible exposures." The precautionary approach is consistent with that mandated by the Stockholm Convention.

4.8.5 Other considerations

237. ECHA (ECHA, 2015a) allows a derogation for existing fire-fighting foams mixtures containing PFOA (including the concentrated ones) placed on the market on or before 4 July 2020, which allows further use for a period of 20 years, taking into account the shelf life. This derogation is consistent with the exemption for foams already in use, and will avoid the need for early replacement of exempted foams.[64] IPEN commented within the RME and discussions at POPRC-13 that the normal lifetime of fire-fighting foam varies considerably with temperature and storage conditions. According to them, 20 years is an inappropriate length of time for continued dispersive use of POPs, a use which

[62] https://toxicfreefuture.org/new-law-protects-drinking-water-firefighters-toxic-perfluorinated-chemicals/.

[63] https://www.theguardian.com/australia-news/2017/oct/18/toxic-firefighting-chemicals-the-most-seminal-public-health-challenge.

[64] UNEP/POPS/POPRC.13/7/Add.2.

United States Environmental Protection Agency
Office of Water Mail Code 4304T
EPA 822-R-16-002 May 2016

Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)

Health Effects Support Document

for

Perfluorooctane Sulfonate (PFOS)

U.S. Environmental Protection Agency
Office of Water (4304T)
Health and Ecological Criteria Division
Washington, DC 20460

http://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information.

EPA Document Number: 822-R-16-002
May 2016

EXECUTIVE SUMMARY

Perfluorooctane sulfonate (PFOS) is a fluorinated organic compound with an eight-carbon backbone and a sulfonate functional group. PFOS-related chemicals are used in a variety of products, including surface treatments for soil/stain resistance; surface treatments of textiles, paper, and metals; and in specialized applications such as firefighting foams. Because of strong carbon-fluorine bonds, PFOS is stable to metabolic and environmental degradation and is resistant to biotransformation. Data in humans and animals demonstrate ready absorption of PFOS and distribution of the chemical throughout the body by noncovalent binding to serum albumin and other plasma proteins. Both experimental data and pharmacokinetic models show higher levels of PFOS in fetal serum and brain compared with the maternal compartments. PFOS is not readily eliminated from humans as evidenced by the estimated average half-life values of 4.1–8.67 years. In contrast, half-life values for the monkey, rat, and mouse are 121 days, 48 days, and 37 days, respectively. The long half-lives appear to be the result of saturable resorption from the kidney. In other words, after initial PFOS removal from blood by the kidney, a substantial fraction of what would normally be eliminated in urine is resorbed from the renal tubules and returned to the blood. A number of published toxicokinetic models use saturable resorption as a basis for predicting serum values in animals and humans, including one developed by the U.S. Environmental Protection Agency (EPA) to support this assessment.

Peroxisome proliferation as a result of binding to and activation of peroxisome proliferator-activated receptor-alpha (PPARα), is usually associated with hepatic lesions in the rat, but some uncertainties exist as to whether this is true for liver effects induced by PFOS. Increased hepatic lipid content in the absence of a strong PPARα response is a characteristic of exposure to PFOS. In two studies, mice administered PFOS showed differential expression of proteins mainly involved in lipid metabolism, fatty acid uptake, transport, biosynthetic processes, and response to stimulus. Many of the genes activated by PFOS are associated with nuclear receptors other than PPARα.

Numerous epidemiology studies have examined occupational populations at large-scale PFOS production plants in the United States and a residential population living near a PFOA production facility in an attempt to determine the relationship between serum PFOS concentration and various health outcomes. Epidemiology data report associations between PFOS exposure and high cholesterol and reproductive and developmental parameters. The strongest associations are related to serum lipids with increased total cholesterol and high density lipoproteins (HDLs). Data also suggest a correlation between higher PFOS levels and decreases in female fecundity and fertility, in addition to decreased body weights in offspring, and other measures of postnatal growth. Several human epidemiology studies evaluated the association between PFOS and cancers including bladder, colon, and prostate, but these data present a small number or cases and some are cofounded by failure to adjust for smoking. The associations for most epidemiology endpoints are mixed. While mean serum values are presented in the human studies, actual estimates of PFOS exposure (i.e., doses/duration) are not currently available. Thus, the serum level at which the effects were first manifest and whether the serum had achieved steady state at the point the effect occurred cannot be determined. It is likely that some of the human exposures that contribute to serum PFOS values come from PFOS derivatives or precursors that break down metabolically to PFOS. These compounds may originate from PFOS in diet and materials used in the home, thus, there is potential for confounding. Additionally, most of the subjects of the epidemiology studies have many perfluoroalkyl substances (PFAS), other contaminants, or both in their blood. Taken together, the weight of evidence for human

studies supports the conclusion that PFOS exposure is a human health hazard. At this time, EPA concludes that the human studies are adequate for use qualitatively in the identification hazard and are supportive of the findings in laboratory animals.

Short-term and chronic exposure studies in animals demonstrate increases in liver weight consistently at doses generally ≥ 0.5 milligrams per kilogram per day (mg/kg/day). Co-occurring effects in these studies include decreased cholesterol, hepatic steatosis, lower body weight, and liver histopathology.

One and two generation toxicity studies also show decreased pup survival and body weights. Additionally, developmental neurotoxicity studies show increased motor activity and decreased habituation and increased escape latency in the water maze test following in utero and lactational exposure to PFOS. Gestational and lactational exposures were also associated with higher serum glucose levels and evidence of insulin resistance in adult offspring. Limited evidence suggests immunological effects in mice.

EPA derived a reference dose (RfD) for PFOS of 0.00002 mg/kg/day based on decreased neonatal rat body weight from the two-generation study by Luebker et al. (2005b). A pharmacokinetic model was used to predict an area under the curve (AUC) for the no observed adverse effect level (NOAEL) and used to calculate a human equivalent dose $(HED)_{NOAEL}$. The total uncertainty factor (UF) applied to the HED_{NOAEL} from the rat study was 30, which included a UF of 10 for intrahuman variability and a UF of 3 to account for toxicodynamic differences between animals and humans. The HED for effects on pup body weight in the two generation study is supported by comparable values derived from the lowest observed adverse effect level for the same effect in the one-generation study and the NOAEL for effects seen in a developmental neurotoxicity study.

Applying the U.S. EPA Guidelines for Carcinogen Risk Assessment, there is *suggestive evidence of carcinogenic potential* for PFOS (USEPA 2005a). In a chronic oral toxicity and carcinogenicity study of PFOS in rats, liver, thyroid, and mammary fibroadenomas were identified. The biological significance of the mammary fibroadenomas and thyroid tumors was questionable as a linear response to dose was not observed. The liver tumors also showed a slight, but statistically-significant increase only in high-dose males and females. The liver tumors most found were adenomas (7/60 and 5/60 in high-dose males and females, respectively, versus none in the controls of either sex). Only one hepatocellular carcinoma was found in a high-dose female. The genotoxicity data are uniformly negative. Human epidemiology studies did not find a direct correlation between PFOS exposure and the incidence of carcinogenicity in worker-based populations. Although one worker cohort found an increase in bladder cancer, smoking was a major confounding factor, and the standardized incidence ratios were not significantly different from the general population. Other worker and general population studies found no statistically-significant trends for any cancer type. Thus, the weight of evidence for the carcinogenic potential to humans was judged to be too limited to support a quantitative cancer assessment.

United States Environmental Protection Agency
Office of Water Mail Code 4304T
EPA 822-R-16-003 May 2016

Health Effects Support Document for Perfluorooctanoic Acid (PFOA)

Health Effects Support Document
for
Perfluorooctanoic Acid (PFOA)

U.S. Environmental Protection Agency
Office of Water (4304T)
Health and Ecological Criteria Division
Washington, DC 20460

EPA Document Number: 822-R-16-003
May 2016

EXECUTIVE SUMMARY

Perfluorooctanoic acid (PFOA) is a synthetic, fully fluorinated, organic acid used in a variety of consumer products and in the production of fluoropolymers and generated as a degradation product of other perfluorinated compounds. Because of strong carbon-fluorine bonds, PFOA is stable to metabolic and environmental degradation. PFOA is one of a large group of perfluoroalkyl substances (PFASs) that are used to make products more resistant to stains, grease, and water. These compounds have been widely found in consumer and industrial products as well as in food items. Major U.S. manufacturers voluntarily agreed to phase out production of PFOA by the end of 2015. Exposure to PFOA in the United States remains possible due to its legacy uses, existing and legacy uses on imported goods, degradation of precursors, and extremely high persistence in the environment and the human body.

Extensive data on humans and animals indicate ready absorption of PFOA and distribution of the chemical throughout the body by noncovalent binding to plasma proteins. Studies of postmortem human tissues identify its presence in liver, lung, kidney, and bone. PFOA is not readily eliminated from the human body as evidenced by the half-life of 2.3 years among members of the general population. In contrast, half-life values for the monkey, rat, and mouse are 20.8 days, 11.5 days, and 15.6 days, respectively.

Human epidemiology data report associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney). Epidemiology studies examined workers at PFOA production plants, a high-exposure community population near a production plant in the United States (i.e., the C8 cohort), and members of the general population in the United States, Europe, and Asia. These studies examined the relationship between serum PFOA concentration (or other measures of PFOA exposure) and various health outcomes. Exposures in the highly exposed C8 community are based on the concentrations in contaminated drinking water and serum measures. Exposures among the general population typically included multiple PFASs as indicated by serum measurements. The correlation among eight carbon PFASs is often moderately strong (e.g., Spearman $r > 0.6$ for PFOA and perfluorooctane sulfonate (PFOS) in the general population). Mean serum levels among the occupational cohorts ranged from approximately 1 to 4 micrograms per milliliter (µg/mL) and in the C8 cohort ranged from 0.01 to 0.10 µg/mL. Geometric mean serum values for the National Health and Nutrition Examination Survey (NHANES) general population (≥ age 12; 2003–2008) were 0.0045 µg/mL for males and 0.0036 µg/mL for females.

These epidemiology studies have generally found positive associations between serum PFOA concentration and total cholesterol (TC) in the PFOA-exposed workers and the high-exposure community (i.e., increasing lipid level with increasing PFOA); similar patterns are seen with low-density lipoproteins (LDLs) but not with high-density lipoproteins (HDLs). These associations were seen in most of the general population studies, but similar results also were seen with PFOS, and the studies did not always adjust for these correlations. Associations between serum PFOA concentrations and elevations in serum levels of alanine aminotransferase (ALT) and gamma-glutamyl transpeptidase (GGT) were consistently observed in occupational cohorts, the high-exposure community, and the U.S. general population. The associations are not large in magnitude, but indicate the potential for PFOA to affect liver function.

September 14, 2022

SUBMITTED VIA E-MAIL

Mr. Michael S. Regan, Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

RE: Proposed Rule - Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances (EPA-HQ-OLEM-2019-0341; FRL-7204-02-OLEM)

Dear Administrator Regan:

The undersigned organizations respectfully request that the comment period for the above referenced rulemaking be extended by 60 days.

EPA requests comment on a number of important issues relating to the proposed designations of PFOA and PFOS under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Given the magnitude and complexity of the proposed rule and its potential impact on the water sector, we believe that a 120-day comment period is necessary to adequately respond to EPA's request for comment and provide a reasonable opportunity for public review.

Furthermore, it is imperative that regulated entities – especially those in the water sector – have time for a thorough examination of the Economic Assessment of the Potential Costs and Other Impacts for the proposed rule. This document has not been previously seen by the public, and our organizations have serious concerns that the assessment significantly underestimates the potential economic costs on the water sector from the proposed rule. It is critical that the water sector have time to accurately determine the potential economic impacts of the proposal and provide that information to EPA so that the rulemaking record is as complete as possible.

We would appreciate a response to this request as soon as possible. Should you have questions or would like to discuss this matter, please contact Kristina Surfus at 202-833-4655 or ksurfus@nacwa.org.

Sincerely,

Kristina Surfus
Managing Director, Government Affairs
National Association of Clean Water Agencies (NACWA)

Adam D. Link
Executive Director
California Association of Sanitation Agencies (CASA)

Claudio H. Ternieden
Chief Policy Officer
Water Environment Federation (WEF)

G. Tracy Mehan, III
Executive Director of Government Affairs
American Water Works Association (AWWA)

Tom Dobbins
CEO
Association of Metropolitan Water Agencies (AMWA)

November 7, 2022

Submitted via www.regulations.gov

Michele Schultz
Office of Superfund Remediation and
Technology Innovation (5202-T)
Environmental Protection Agency
1200 Pennsylvania Avenue NW,
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OLEM -2019-0341
Designation of Perfluorooctanoic (PFOA and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, Proposed Rule, 87 Fed. Reg. 54,415 (Sept. 6, 2022)

The American Farm Bureau Federation appreciates the opportunity to submit these comments to the U.S. Environmental Protection Agency ("EPA") in response to its proposed rule to designate Perfluorooctanoic (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA "hazardous substances." *See* 87 Fed. Reg. 54,415 (Sept. 6, 2022).

The American Farm Bureau Federation is the Voice of Agriculture®. We are farm and ranch families working together to build a sustainable future of safe and abundant food, fiber and renewable fuel for our nation and the world. The livelihood of farmers and ranchers depends on healthy soil and groundwater. We support EPA's underlying goal of addressing widespread contamination of the environment caused by historic use of PFOA and PFOS. Unfortunately, EPA's proposed designation of PFOA and PFOS as CERCLA hazardous substances overlooks the consequences on farmers and ranchers as the owners of contaminated property.

EPA should withdraw this proposed rule as urged by AFBF and many other organizations in a letter dated October 19, 2022 for the reasons explained in detail in that letter and in these comments. Instead of listing PFOA and PFOS as a "hazardous substance," EPA should continue to expand as appropriate the use of its existing CERCLA removal and Safe Drinking Water Act authorities to address acute circumstances of PFOA and PFOS contamination in soil and groundwater. EPA retains complete authority and enforcement discretion in the use of these existing authorities. EPA should also be clear in its continued support of farmers and ranchers using biosolids beneficially on their lands. Further, EPA should continue to conduct its own research, and support research conducted by others to develop and enhance treatment and destruction technologies as well as reliable analytical methods as outlined in EPA's PFAS Roadmap[1].

AFBF supports the protection and restoration of land and groundwater

Farmers and ranchers support the protection and restoration of land and groundwater and the efforts that EPA is making in the PFAS Roadmap to address the impacts of the historic use of PFAS chemicals. The livelihood of farmers and ranchers depends on healthy soil and

[1] PFAS Strategic Roadmap: EPA's Commitment to Action 2021- 2024, October 2021 (PFAS Roadmap).

groundwater. American's families and the rest of the world rely on food, fuel and fiber produced by American farmers and ranchers. Farmers and ranchers have not knowingly used PFOA and PFOS in their operations. Farmers and ranchers are in no position technically, economically or practically to address the impact of the presence of PFAS chemicals and especially PFOA and PFOS which continue to be found in virtually any place where soil, surface and groundwater has been tested.[2]

EPA's proposed rulemaking and administrative record fails to fully consider the appropriateness of using CERCLA remedial authority to address the apparent ubiquitous presence of PFAS contamination and how the application of CERCLA's remedial authority imposing strict liability on the largest landowning segment of the economy—farmers and ranchers. PFOA and PFOS poses more technical challenges than two other widely found contaminants that have been designated as a CERCLA "hazardous material," PCBs and dioxin. PFAS chemicals pose a greater challenge because these chemicals are more mobile so in addition to contaminating soil, PFAS chemicals contaminate surface and groundwater to much greater degree than PCBs or dioxin.

PFOA and PFOS have come onto agricultural land through no knowledge or fault of farmers or ranchers

PFOA and PFOS are believed to come onto agricultural land through a few different mechanisms. First, these chemicals can be found in high quantities in firefighting foam that is used in and around airports and Department of Defense (DoD) training facilities. These chemicals have been known to travel naturally through the environment—most notably through ground and surface waters—and can eventually be deposited onto farm fields. Proximity to one of these areas can lead to elevated levels of PFAS.

Another way PFAS chemicals are delivered to farms is through the use of biosolids. Biosolids are commonly applied to farm fields as an alternative to fertilizer. A farmer accepts biosolids from a wastewater treatment facility to land apply onto their property. Biosolids are regulated at the federal, state, and local level to ensure protection of public health and the environment. For decades, the EPA has encouraged and supported farmer's beneficial use of biosolids. Unfortunately, more recently, we have learned that biosolids are contributing to the spread of PFAS on agricultural lands. This is a major concern for our members and these comments will elaborate on it further.

Pesticide holding containers have also been identified as a potential source of PFAS on farms. Recent EPA data indicates that plastic containers made of fluorinated high-density polyethylene (HDPE) are likely to leach PFAS into pesticides and other liquid products that are stored in them. EPA's review also suggests that the amount of PFAS that migrates into liquid products increases with storage time.

[2]*See e.g.*, 87 Fed. Reg. 54415, September 6, 2022 (Proposed Rule preamble) at 55,426 – 55,428. *See also*, study cited in footnote 39.

Regardless of how PFAS ultimately arrives onto a farm field, it is undeniable that the fault does not fall on our nation's farmers and ranchers. It is worth acknowledging, yet again, that farmers do not use PFAS chemicals in any part of their operations and are innocent receivers.

EPA's proposal to use its CERCLA remedial authority is the wrong tool proposed to be used at the wrong time

EPA's proposal to exercise its never before used CERCLA remedial authority to designate PFOA and PFOS as CERCLA hazardous substances to address the ubiquitous contamination of the environment, including agricultural lands, is the wrong tool to deploy at this time.

A. **Designating PFOA and PFOS as hazardous substances creates liability risk for farmers and ranchers, does not compensate them for their economic losses, and threatens the long-used application of biosolids**

i. **CERCLA has no ability to compensate or protect loss of agricultural land value because it does not provide a claim for economic damage recovery**

CERCLA is not a tool that addresses the potential loss of use and value to farm and ranchland from PFAS contamination. Instead, CERCLA causes of action only provide for clean-up costs incurred in compliance with the National Contingency Plan. However, farms and ranches are unlikely to ever receive the benefit of a clean-up, meaning a CERCLA designation will reduce agricultural land value and use potential without providing any corresponding relief. Ironically, a listing may hinder regulators and legislators from actually addressing the issue of contamination because of a common misunderstanding of how CERCLA operates.

Farmers and ranchers have not knowingly contributed to the presence of PFOA or PFOS chemicals on their lands. Yet, the threat of contamination can diminish or even destroy the value of the agricultural land and production. There are an increasing number of reports illustrating how the contamination of the soil and groundwater on farms with PFOA and PFOS has devastated farming operations These reports highlight the commonly understood notion that farmer's livelihoods are completely reliant on the health of their land.

As the largest landowning sector of the economy, farmers and ranchers have experienced more potential damage to their livelihood than any other sector of the economy and unlike other sectors are not in a position to pass along higher costs. As explained below, CERCLA's strict liability scheme can impose potential liability on farmers or ranchers as the owners of contaminated property, but it does not provide a way for farmers and ranchers to recover the value of their economic losses created by the contamination that they did not "cause."

One devastating example of the impact that PFAS contamination can have on farmers is from the Grostic Cattle Company in Brighton, Michigan. The company, operated by Jason Grostic and his family, is a 300-acre beef farm approximately 50 miles northwest of Detroit. The Grostic family sold beef from their 120-head herd primarily at farmers markets, private purchases of freezer

beef, and to local businesses and schools.[3]. Because the farm was operated using minimal inputs, Jason did not purchase conventional fertilizer for his pastures, hay, or silage, but instead fertilized with manure from his own cattle and from treated biosolids from a local wastewater treatment facility, regulated and tested by the State of Michigan through its biosolids rules.[4]

The Wixom Wastewater Treatment Plant, the wastewater facility supplying Grostic Cattle Company's biosolids, tested its biosolids at Michigan PFAS Action Response Team's (MPART) direction and found that the biosolids contained PFOS concentrations as high as 2,150 parts per billion, likely from a chrome plating operation in the city. The Wixom facility was instructed to halt land application of biosolids. However, because of the high PFAS sampling results, the MPART team began testing the sites that had accepted biosolids from Wixom, including the Grostic Cattle Company's land.[5]

With the voluntary cooperation of the Grostic family, MPART contractors sampled surface water, tile drain outlets, nested groundwater monitoring wells, as well as soil, forage, haylage, and silage from Jason's farm. They additionally tested four nearby residential wells. The drinking water samples tested were non-detect for any PFAS compounds. Two of the shallow groundwater monitoring wells contained detectable levels of PFAS, but the concentration was below Michigan's drinking water criteria.[6] 12 of the 13 surface water sites, consisting of standing water from Grostic Cattle Company's fields along with four small ponds on the property, had PFOS levels above surface water criteria, the highest result with a PFOS concentration of 533 parts per trillion (ppt).[7]

MPART advised Jason that because crop and soil samples had elevated levels of PFAS above comparable background levels, they should have the cattle tested. Samples were sent to the USDA laboratory in St. Louis, MO. PFOS concentrations in the meat samples, sirloin steaks, chuck and English roasts contained PFOS at concentrations between 0.98 and 2.48 ppb.

The MPART team and the Governor's office issued a seizure order for all cattle and products from the farm.[8] The family could not move them or sell any of the products. The State of Michigan issued a press release and contacted Grostic Cattle Company customers directly,

---

[3] 2022. Grostic Cattle Company. Retrieved from: https://www.facebook.com/pages/category/Agriculture/Grostic-Cattle-Company-917482395307701/. *See also* https://www.dtnpf.com/agriculture/web/ag/livestock/article/2022/05/06/michigan-farm-cautionary-tale-pfas

[4] 2022. Michigan Administrative Rules. Part 24: Land Application of Biosolids. R 323.2401 to R 323.2418. Retrieved from: https://ars.apps.lara.state.mi.us/AdminCode/DownloadAdminCodeFile?FileName=R%20323.2401%20to%20R%20323.2418.pdf&ReturnHTML=True.

[5] 2022. Michigan PFAS Action Response Team. Wixom WWTP Biosolids Fields Area of Interest (Wixom, Livingston County). Retrieved from: https://www.michigan.gov/pfasresponse/investigations/sites-aoi/livingston-county/wixom-wwtp-biosolids-fields-area-of-interest.

[6] 2020. Michigan PFAS Action Response Team. Maximum Contaminant Levels. Retrieved from: https://www.michigan.gov/pfasresponse/drinking-water/mcl.

[7] 2021. Michigan Department of Environment, Great Lakes, and Energy. Statewide Wastewater Treatment Plant and Biosolids PFAS Study. Retrieved from: https://www.michigan.gov/-/media/Project/Websites/egle/Documents/Programs/WRD/Biosolids/PFAS-Biosolids-Field-Reports-Summary-WRD.pdf?rev=46ca463cf970481dbc86162c002cac12.

[8] Personal communication with Jason Grostic, January 27, 2022.

advising them they could return the beef for a refund, and instructing the public that although there is no state or federal standard for PFAS in food, an increased exposure to PFAS compounds could cause health impacts.[9]

Jason Grostic and his family were devastated. Jason spoke with his state and national Representatives, but for months after the seizure he and his family were trapped in limbo. Cattle and beef couldn't be sold and the forage and crops on the farm appeared to be one of the sources of the cattle's PFAS exposure, so the Grostic family was instructed to try not to feed the cattle from their own stored hay, grazing, and silage. This meant the farm began bleeding money as they had no revenue and skyrocketing feed costs, while their lender who held the notes on additional land and equipment the Grostic family had recently purchased to expand the farm began pressuring the Grostics to come up with some guarantee of their ability to repay those loans. Legislators were unable to bring appropriations bills to the floor that might have provided the farm with financial assistance during this time.

Jason provided an estimate of the total costs of losing access to his land for grazing and capacity to grow feed for his herd, building manure storage, disposing of the contaminated feed, and an estimate for laying concrete to convert the farm to a feed lot and purchase feed and hay for them. The total ran to more than $10 million[10] and the State of Michigan had no authorization to provide him additional financial assistance, nor does the State have statutes providing for indemnification of the loss of livestock or farmland due to chemical contamination. Michigan State University also sought funding to study the situation on the Grostic Farm but was unable to secure enough research funding to provide the Grostics any assistance. By June Jason was forced to sell his farming equipment to keep his family and the cattle supported.[11]

ii. EPA Cannot Offer Protection from CERCLA Remedial Liability to Farmers and Ranchers as Landowners

Under CERCLA's remedial authority, EPA is unable to limit the focus of cleanup obligations from historic PFOA and PFOS use on particular parties. The designation of PFOA and PFOS as CERCLA "hazardous substances" will automatically trigger the imposition of CERCLA liability on four broad classes of parties. Especially relevant to farmers and ranchers who have unknowingly and unintentionally allowed PFOA and PFOS contaminated materials to be deposited on their properties is that CERCLA imposes liability on current and previous owners of contaminated property. This may mean that current farmers and ranchers who own agricultural lands contaminated with PFOA and PFOS as well as retired farmers and ranchers who sold contaminated land may be potential liable parties under CERCLA to subsequent

---

[9] 2022. Michigan Department of Agriculture and Rural Development. Consumption Advisory: Grostic Cattle Company of Livingston County Beef Sold Directly to Consumers May Contain PFOS. Retrieved from: https://www.michigan.gov/mdard/about/media/pressreleases/2022/01/28/grostic-cattle-company-of-livingston-county-beef-sold-directly-to-consumers-may-contain-pfos. 2022. Michigan PFAS Action Response Team. MPART investigation yields new data on PFAS. Retrieved from: https://www.michigan.gov/pfasresponse/about/news/2022/01/28/mpart-investigation-yields-new-data-on-pfas.

[10] Personal communication with Jason Grostic, February 15, 2022.

[11] Personal communication with Jason Grostic, June 2022.

owners and developers of agricultural property who incur cleanup costs.[12] This is yet another example of why this rulemaking is an inappropriate place to start in addressing PFAS concerns.

A landowner with CERCLA hazardous substances on the property is strictly liable under CERCLA by operation of law and not by virtue of an EPA administrative act. Knowledge of the presence of CERCLA hazardous substances is not a defense, and EPA has no ability to shield any parties that come within CERCLA's statutory definition of responsible parties from potential CERCLA remedial liability. The past 40 years of the Superfund program have demonstrated that EPA's intention to use its enforcement discretion is not binding on EPA nor is it a restraint on CERCLA cost recovery litigation brought by third parties that will be enabled immediately by this rulemaking. CERCLA provides few effective defenses to remedial liability.

EPA currently has CERCLA removal authority to address PFOA and PFOS contamination which can be used in a more targeted manner that does not rely on these chemicals being designated as "hazardous substances." Specifically, EPA can use its CERCLA removal authority to respond to contamination based on PFOA and PFOS being "pollutants and contaminants."[13] EPA has complete discretion on the use of this component of CERCLA authority because it is limited to EPA and other designated federal agencies. To do this, EPA has to make a finding that the presence of the pollutants or contaminants is an "imminent and substantial" threat.[14] Based on CERCLA's 40 year history, this is not a high threshold to meet and has not inhibited EPA's ability to take prompt action.[15] Importantly, in contrast to CERCLA remedial authority and its automatic imposition of liability, EPA does have to make a finding to use this removal authority.

iii. Biosolids are a valuable low-cost fertilizer and there is not a good alternative to land application

EPA must first consider and resolve how a listing decision will impact the use of biosolids on agricultural land. EPA has long encouraged and supported the application of biosolids to agricultural property as a valuable low-cost means of managing biosolids. While beneficially used on farm fields, it also prevents these substances from taking up landfill space or requiring expensive and energy-intensive treatment and disposal. EPA's proposed rule ignores the impact that the CERCLA designation will have on this long-term and widespread practice and the absence of practical available alternatives. The placement of a CERCLA hazardous substance on property automatically creates potential remedial liability for the parties involved in the transportation and placement of the hazardous substances on the land, as well as the landowner.

The PFAS Roadmap proposes developing a biosolids risk assessment, which could be the basis for a future biosolids regulatory standard, as one of its last proposed actions (Winter 2024). A biosolids disposal standard might provide a CERCLA defense to the biosolids liability going

---

[12] Under CERCLA Section 107(a) the following parties are liable "(1) the owner and operator of a vessel or a facility
(2) any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of…." 42 USC 9607(a).

[13] 42 USC 9604 (1)(B).

[14] *Ibid*.

[15] Superfund Removal Guidance for Preparing Action Memorandum, SEMS Doc ID 190041September, 2009. https://semspub.epa.gov/work/HQ/190041.pdf

forward, but would not provide liability relief retrospectively. The administrative record for this rule fails to consider the implication on the management of biosolids retrospectively and prospectively.[16] We hope that biosolids can continue to be available as a viable fertilizer option. However, designating these chemicals as a "hazardous material" before setting a regulatory standard for biosolids is very concerning. It is important for farmers to feel safe and confident in taking biosolids for beneficial use, and, therefore, EPA must address these concerns imminently.

B. EPA's proposal to use its CERCLA remedial authority does not include a careful analysis of how it compares with other existing authorities to address PFOA and PFOS contamination

EPA's proposed designation of PFOA and PFOS does not include a careful analysis of how its other existing authorities have been and can continue to be used to address widespread contamination of PFOA and PFOS in comparison with the implementation of CERCLA remedial authority. In particular, the preamble does not address how three existing authorities are already well suited to accomplish EPA's goals: (1) existing CERCLA removal authority; (2) Safe Drinking Water Act orders; and (3) RCRA corrective actions.[17] For example, EPA did not explain what significant limitations it has encountered with respect to using these existing authorities to address PFOA and PFOS contamination. In fact, CERCLA removal authority has allowed EPA to conduct PFOA and PFOS cleanups. Safe Drinking Water Act orders to responsible parties have compelled action to address contaminated drinking water. RCRA corrective action is another authority that EPA and authorized states have to address PFOA and PFOS contamination from industrial and waste management sources. EPA has proposed to further clarify RCRA corrective action authority by adding PFOA, PFOS and potentially other PFAS chemicals to the RCRA Appendix VIII.[18]

A careful analysis by EPA would have provided a detailed description of the existing authorities and their strengths, benefits, and limitations in comparison to the designation of PFOA and PFOS as CERCLA hazardous substances. While EPA does identify its use of CERCLA removal authority in the preamble, it fails to compare and contrast its exercise of that authority against the additional authority that would be gained by the PFOA and PFOS CERCLA designation in any meaningful or practical manner. For example, EPA in recent years has more frequently relied upon its removal authority to address lead contamination, even though lead is a CERCLA hazardous substance, to most rapidly and effectively address acute residential human exposure to lead. EPA has also used its removal action authority as the basis for entering consent orders with parties to conduct cleanups while also requiring those parties to reimburse EPA for its costs. In such cases, EPA can recover its costs without exercising its remedial authority.

---

[16] EPA Assistant Administrator for the Office of Water Radhika Fox's statements on biosolids. "I will certainly say the issue of biosolids and PFAS is an absolute frontier issue," Fox said Oct. 11 during WEFTEC 2022, the annual conference of the Water Environment Federation (WEF). Her remarks were livestreamed from New Orleans, LA. Reported in *Inside EPA*, October 11, 2022.

[17] Proposed Preamble at 54436.

[18] *See*, Letter from EPA Administrator Michael Regan to Governor Lujan Grisham of New Mexico, dated October 26, 2021, announcing intention to initiate the rulemaking to add POFA, PFOS, PFBS and GenX as RCRA Hazardous Constituents to 40 CFR Part 261 Appendix VIII and a rulemaking to clarify that RCRA Corrective Action provides the authority to require the investigation and cleanup of wastes that meet the statutory definition of hazardous waste under RCRA Section 1004(5).

EPA could have compared how addressing PFOA and PFAS contamination under CERCLA compares with addressing it under RCRA. This comparison would have been an evaluation of reasonable alternatives to the proposed CERCLA designation rule as well as being relevant to EPA's response to pending RCRA petitions before the Agency. EPA has a pending petition from the State of New Mexico as well as at least two environmental NGOs, seeking to have PFOA, PFOS and other PFAS chemicals regulated under RCRA.[19] EPA has not responded to New Mexico within the 90-day statutory timeline for responding to a state's RCRA regulatory request to decide whether it will or will not precede to conduct a RCRA rulemaking.

Under RCRA, which unlike CERCLA is a regulatory statute, EPA could carefully craft the regulation of PFOA, PFOS, and other PFAS chemicals and not have it apply simply to the presence of chemicals at any concentration from any source. For example, EPA could focus the regulation of PFOA and PFOS from certain sources (e.g. manufacturers) as well as from certain sources (e.g. the use of AFFF) and only regulate the chemicals that are above a certain concentration threshold. In addition, under RCRA, EPA has the authority it does not have under CERCLA to provide exemptions from regulations. RCRA regulation of PFOA and PFOS would achieve the same goals as this rulemaking and do much more. For example, chemicals regulated under RCRA automatically become CERCLA hazardous substances. More importantly, RCRA could do much to address the remediation of PFOA and PFOS and the management of PFOA and PFOS contaminated materials. RCRA provides for a comprehensive national management scheme for RCRA hazardous wastes. CERCLA does not regulate the management of CERCLA hazardous substances. EPA has experience with RCRA rulemaking designating particular wastes as RCRA hazardous waste, but it has never designated a chemical directly as a CERCLA hazardous substance. EPA has announced its intention to conduct the first step in the RCRA regulation of PFOA and PFOS, which is to add those chemicals to Appendix VIII of RCRA[20], but has not made a time commitment, even in the face of a statutory deadline to respond to New Mexico, to further pursue RCRA regulation.

EPA has announced that it plans to regulate PFOA and PFOS under both the Safe Drinking Water Act (SDWA) and the under the National Pollutant Discharge Elimination System (NPDES) program under the Clean Water Act. Both of these authorities are regulatory authorities that will establish regulatory limits and will need to consider treatment technologies as part of the rulemaking process. The SDWA regulation will address PFOA and PFOS contamination in drinking water and drinking water sources. The NPDES regulations will address PFOA and PFOS contamination in some manner yet to be announced by EPA in water discharges that are subject to Clean Water Act jurisdiction. EPA has considerable experience in regulating chemicals under both of these regulatory schemes. EPA could have analyzed how these regulatory actions once implemented would impact the need for the CERCLA designation of PFOA and PFOS as CERCLA hazardous substances. In addition, EPA could have analyzed the impact of CERCLA designation of PFOA and PFOS on these Clean Water Act regulations as the liability associated with the handling and disposal of CERCLA hazardous substances will

---

[19] The New Mexico petition was dated June 23, 2021 and so 90 days was September 21, 2021. The petition was submitted pursuant to 42 U.S.C. Section 6921(c).

[20] *See*, footnote 9.

complicate and increase the costs of handling residues of treating drinking water, stormwater and wastewater.

C. The proposal fails to consider the additional costs and burdens due to the existing technical challenges

All parties potentially facing CERCLA liability under this proposal will face technical challenges understanding their potential liability. It is difficult to know how they might seek to address and resolve that potential liability because of the current lack of a full suite of approved analytical methods and approved destruction, disposal, and cleanup standards and technologies.

i. The lack of a complete approved suite of analytical methods hampers the ability to understand the potential extent of liability and conduct an effective cleanup

There are many reasons that the timing of this rulemaking is problematic and, at least in the near term will raise questions that cannot at present be answered. In particular, there are gaps in the current suite of analytical methods that preclude a proper investigation and remediation of PFOA and PFOS contamination and likewise prevent potentially responsible parties from assessing their potential liability. While EPA's PFAS Roadmap does address the eventual development of analytical techniques,[21] the proposal does not acknowledge the reality that we do not currently have the necessary technology. For example, current approved analytical techniques allow for the measurement of PFOA and PFOS concentration in groundwater, although not down to the level of EPA's current Safe Drinking Water Act health advisory limit. Similarly, there are no EPA approved analytical methods for accurate measurement of concentrations in soil as well as EPA soil concentration limits necessary for the protection of groundwater. The lack of a discussion in the preamble about the relevance of these analytical standards and reference values is concerning since these are essential components to a CERCLA cleanup. EPA fails to explain why it is necessary or advantageous to impose CERCLA liability now on parties in advance of those parties being able to understand, estimate their liability and conduct an effective soil and other environmental media cleanup.

ii. The lack of approved treatment and disposal methods limits the ability to plan, conduct and complete remediation

In addition to technical gaps preventing the accurate detection and quantification of PFOA and PFOS, there are no approved treatment and disposal methods for PFOA and PFOS contaminated soil, surface, and groundwater. EPA is required by law to issue and update guidance on PFAS destruction and disposal technology. In response to this Congressional statutory mandate, EPA issued the first Destruction and Disposal guidance document on December 18, 2020.[22] The

[21]The PFAS Roadmap states that during the Fall of 2022 "EPA and DoD are continuing this collaboration to complete a multi-laboratory validation of the method. EPA expects to publish the multi-lab validated method online by Fall 2022. Following the publication of the method, EPA will initiate a rulemaking to propose the promulgation of this method under the Clean Water Act (CWA). "PFAS Roadmap, page 15. EPA also says it will release analytical technics for monitoring drinking water in the Fall of 2024. *Ibid.*

[22] Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances, December 18, 2020

document did not provide guidance in the sense of recommending treatment methods and treatment limits; rather, it summarized the current state of different technologies.[23] Work continues on the development of destruction and disposal technologies, but all EPA has committed to is issuing the second edition of the destruction and disposal guidance in December 2023, which is the statutory deadline. However, this is merely guidance and will not have the same impact as issuing generally applicable regulatory management standards, which would happen if EPA regulated PFOA and PFOS waste under its RCRA authority.

iii. EPA's current draft drinking water health advisory limit and its uncertain status further complicate implementation of cleanup

In EPA's December 9, 2019, guidance memorandum, *Interim Recommendations to Address Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctanesulfonate*, EPA provides guidance addressing groundwater used as a drinking water source at sites being cleaned up under federal authority. This guidance incorporated the former health advisory limit (HAL) from EPA's drinking water program as the de facto cleanup standard. Further, EPA explained that in the event EPA were to adopt a Maximum Contaminant Level (MCL) for PFOA and PFOS under the Safe Drinking Water Act, the MCL would in effect replace the HAL. The PFAS Roadmap states EPA intends to propose a MCL in the Fall of 2022 and finalize it in the Fall of 2023.[24] EPA has sent proposed MCLs and MCLGs to OMB for interagency review.

EPA has not revised the December 2019 groundwater memorandum, but EPA issued a revised HALs in June 2022 of .004 ppt (PFOS) and .02 ppt (PFOA) that is more than 17,500 and 3,500 times less than the prior HAL of 70 ppt that applied to both PFOS and PFOS individually and to a combination of those two PFAS chemicals. The new HAL is well below the value that laboratory methods can accurately quantify. Stated differently, drinking water analyzed at present time as not having detectable concentrations of PFOA and PFOS may in fact have concentrations well above the current HAL.

The World Health Organization (WHO) recently proposed drinking water standards of 100 ppt. This would be comparable to the prior 2016 HAL of 70 ppt and may be more in line with what EPA may propose for drinking water limits. It is also worth noting that a number of states[25] and

https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf (Destruction and Disposal Guidance).

[23] Destruction and Disposal Guidance, page 3.

[24] PFAS Roadmap, page 12.

[25] *See e.g.* the following state information as examples*:*

1.PFAS Testing of Minnesota Community Water Systems, Minnesota Department of Health: https://mdh.maps.arcgis.com/apps/MapSeries/index.html?appid=63515695237f425ea7120d1aac1fd09a;

2. State of Michigan's Statewide PFAS Survey of Public Water Supplies:https://www.michigan.gov/pfasresponse/drinking-water/statewide-survey;

3. Illinois Environmental Protection Agency's PFAS Statewide Investigation Network: Community Water Supply Sampling: https://www2.illinois.gov/epa/topics/water-quality/pfas/Pages/pfas-statewide-investigation-network.aspx; and

4. South Carolina Department of Health and Environmental Control, "PFAS Sampling Results": https://scdhec.gov/BOW/pfas-sampling-results.

the Department of Defense[26] have conducted a considerable number of evaluations of drinking water sources. This data provides strong evidence that at the prior HAL of 70 ppt there are a finite number of groundwater sources used for drinking water to address.

The inability to determine whether drinking water meets the current HAL or the soon to be proposed MCL creates additional unnecessary uncertainty about the potential impact of costs associated with the proposed CERCLA PFOA and PFOS designation. If EPA delayed this proposal until there was a final MCL, it would be possible to make some projections not possible at present about the costs and time needed to address drinking water contamination under CERCLA's remedial authority.

D. Other Technical Failings of the Proposed Rule

The proposal ignores the 40-year history of CERCLA implementation in its analysis of the rule's impacts, benefits, and costs.

i. The proposal cannot support its claim that it will hold PFOA/PFOS manufacturer's liable

The preamble talks about holding liable those parties who manufactured and released significant amounts of PFOA and PFOS. But CERCLA liability is not limited to addressing manufacturers. In fact, CERCLA provides no direct cause of action against a manufacturer of PFOA and PFOS who sold those chemicals to others for use and incorporation into other products.[27] EPA makes the assertion that the CERCLA designation will hold manufacturers responsible without acknowledging the fact that there were very few manufacturers and manufacturing sites that produced PFOA and PFOS. EPA does not consider RCRA corrective action authority as an alternative tool to use with respect to manufacturers. Further, 40 years of CERCLA case law has established that when those manufacturers sold a useful product to a third party, those manufacturers are not liable for the CERCLA cleanup obligation of the downstream users.[28] CERCLA imposes liability without regard to manufacturing, control or knowledge of the presence of PFOA and PFOS. The CERCLA designation of PFOA and PFOS of hazardous substances has the potential to impose CERCLA liability on parties who own land where those chemicals have come to rest after circulating in the environment for decades and even though those landowners had no hand in the manufacture or intentional use of these chemicals.

ii. The proposal does not address the profound challenges and unintended consequences of applying CERCLA remedial authority to a contaminant that is found everywhere

---

[26] Memorandum for Assistant Secretary of the Army (Installations, Energy and Environment) from the Deputy Assistant Secretary of Defense for Construction, "Public Disclosure of Department of Defense Testing Results of Per-and-Polyfluoroalkyl Substances in Drinking Water Within a Covered Area," April 26, 2022, available at: https://media.defense.gov/2022/Apr/27/2002985404/-1/-1/0/MEMO-PUBLIC-DISCLOSURE-POLICY-SECN-345-OF-FY22-NDAA.PDF

[27] *Burlington Northern and Santa Fe Ry. Co. v. United States*, 556 U.S. 599 (2009).

[28] *Ibid*.

While EPA's proposed designation references the widespread finding of PFOA and PFOS not only across the United States, but globally, it does not address how this impacts the use of CERCLA. Analyzed in the CERCLA context highlights the inadequacy and poor fit CERCLA remedial authority is for addressing the problem. For example, if all land is contaminated with PFOA and PFOS, where does "clean" soil come from to replace "contaminated" soil?

The proposal fails to address how CERCLA remedial authority and attendant liability is supposed to work in the context of contaminants that can and have been found virtually any and everywhere where they have been sampled.[29] This is not like the finding of chemicals in particular places resulting from the improper management of chemical wastes from manufacturing, waste treatment, and other particular sources. CERCLA was adopted because RCRA, which was adopted four years earlier, had not yet gone into effect, and had not been able to regulate the storage, treatment, and disposal of hazardous wastes. That is, CERCLA was intended to address the legacy of inappropriately managed hazardous wastes at particular sites primarily caused by historic waste management practices that existed in the absence of modern, nationally applicable pollution prevention requirements enforced by EPA and the states.

The original core environmental statutes such as the Clean Air Act, Clean Water Act, RCRA, and the Toxic Substances Control Act (TSCA) were adopted by Congress to address most broadly contamination in the air, water, and on land by the way of imposing pollution controls. The regulation of what products could be sold and distributed to avoid widespread contamination and unsafe human and environmental exposure is the core of TSCA. These core environmental statutes were designed in part to reduce or eliminate the background concentrations of harmful contaminants. CERCLA was designed to address releases that created the need for immediate action to address particular sites with high level of contaminants. Once again, this only further supports the notion that CERCLA is the wrong tool to be using and there are other, more appropriate environmental statutes that need to be deployed first.

iii. EPA simply asserts cleanups will be faster but does not provide support as to why using remedial authority will be faster than continuing to use its CERCLA removal authority and other authorities

EPA identifies the designation of PFOA and PFOS as a means to designate an area as a site on the National Priorities List (NPL) and that somehow, the placement of a site on the NPL will lead to faster cleanups. EPA simply asserts cleanups will be faster but provides no authority or support for the proposition. EPA side steps the fact that it can, does, and has implemented its CERCLA removal authority much faster than CERCLA's multi-year remedial process, which includes the administrative rulemaking required to add a site to the NPL. The CERCLA remedial process has proven to be a slow multi-step process that takes years if not decades to complete.[30] Further, EPA's position is that it can designate sites for inclusion on the NPL based on the

---

[29] *See* e.g. Proposed Preamble at 55,426 – 55,426. *See also*, study cited in footnote 39.

[30] *See e.g.* the media report about the possibility EPA might seek to list a site in Ann Arbor, Michigan that the state has been working on for decades and which could take EPA two years of time to go through the administrative process to list the site on the NPL and then 7 years to conduct a remedial investigation and feasibility study. https://www.mlive.com/news/ann-arbor/2019/05/ann-arbor-at-pivotal-point-with-gelman-dioxane-plume.html

presence of "pollutants and contaminants" and not just because of the presence of designated hazardous substances.[31]

iv. Cost recovery has not been demonstrated to be a significant need

EPA touts the ability to conduct cost recovery against responsible parties as a benefit of CERCLA designation without providing any analysis of whether the lack of such authority has hindered its current ability to address PFOA and PFOS contamination in a meaningful way. In fact, EPA would not have such authority and does not need it against the Department of Defense (DoD). If EPA had included an analysis of the work it has accomplished to date without a PFOA and PFOS hazardous substance designation, it would show that the EPA has successfully forced known sources of contamination, such as DoD facilities, airports, and many manufacturers to address groundwater as a drinking water source contamination. State environmental agencies, state laws and regulations,[32] as well as private party litigation are also imposing PFAS cleanup requirements. Further, EPA does not address the reality of 40 years of the implementation of Superfund, which shows that cost recovery from potentially responsible parties leads extensive litigation and transaction costs at Superfund sites.

v. Required release reporting's value has been overstated as it is unlikely EPA will receive many PFOA or PFOS release reports

EPA identifies the regulatory requirement to report a release of one pound of PFOA or PFOS, if those chemicals become CERCLA hazardous substances, as a particular benefit of the proposed rulemaking. As EPA knows from 40 years of CERCLA implementation, most CERCLA release reports do not require an immediate response. When a release of a CERCLA designated chemical occurs and merits an immediate response, EPA has the authority to respond using its CERCLA removal authority. It appears to be unlikely that EPA would ever receive many release reports of releases of one pound of PFOA or PFOS, as when those chemicals are present in the parts per trillion level (or even the part per billion level) the quantity of material that would have to be released to exceed the one pound threshold in a 24-hour period would be enormous. It is certainly possible that the intentional use or unintentional release of older AFFF containing PFOA or PFOS could trigger a release report as those chemicals could be present as a percentage of the firefighting foam.[33] Unfortunately, EPA does not provide any information on the number of old AFFF systems still in place at DoD facilities, airports, and fire departments. Further, as the risk of release of PFOA and PFOS associated with the use of AFFF has become better understood, there are new procedures in place for management of discharged AFFF that previously did not exist. These procedures mitigate the impact of AFFF discharges on the environment. EPA could consider, for example, how many release reports it has received for dioxin, which shares a one-pound RQ and is frequently present in parts per trillion levels, to

---

[31] *See e.g.* the Saint-Gobain Performance Plastic Village of Hoosick Falls, New York Superfund site that is on the NPL and a driver of the listing of the site was the presence of PFAS chemicals. https://cumulis.epa.gov/supercpad/SiteProfiles/index.cfm?fuseaction=second.cleanup&id=0202702.

[32] The Interstate Technology Research Council (ITRC) PFAS website collects and updates various state water and soil standards. https://pfas-1.itrcweb.org/fact-sheets/.

[33] 10 billion parts per trillion is 1% of something translated into parts per billion.

assess the likelihood of receiving many, if any, release reports exceeding the one-pound reportable quantity.

vi. The proposal provides no support for its claim that CERCLA will encourage better management of PFOA and PFOS

The proposal makes the unsupported assertion that the CERCLA designation of PFOA and PFOS will encourage better management of these chemicals. But not only does the proposal fail to explain how this better management will happen, it fails to comprehensively address how PFOA and PFOS contaminated materials should be managed and disposed. The proposal further fails to explain how the CERCLA designation will work with the ever-growing patchwork of state requirements that address the management of PFOA and PFOS contaminated materials.

vii. The proposal does not explain the limitations of EPA's enforcement discretion

The proposal identifies EPA's enforcement discretion not to pursue cost recovery litigation and seek to focus it cleanup efforts on certain parties, but does not explain that EPA is not itself bound or constricted by these policies. Furthermore, third parties are not bound by EPA's proposed intention to limit which parties are held responsible for PFOA and PFOS related remedial response costs. Upon the designation of PFOA and PFOS as CERCLA hazardous substances, cost recovery litigation becomes available to any qualifying responsible party. EPA's enforcement discretion is no solution to the statute's strict and automatic application of liability, which frequently causes foreseeable litigation chain reactions. For example, EPA routinely has sought to compel particular parties to be responsible for CERCLA response costs and to perform remedial work, which triggers those parties to sue other parties not targeted by EPA, but who the targeted parties think contributed to the contamination and associated remedial costs. This sequence of events is particularly likely because there can be so many potential sources of PFOA and PFOS contamination in the vicinity of suspected sources of the contamination. Unfortunately, the use of EPA's enforcement discretion would only provide cold comfort for our nation's farmers and ranchers because it does not guarantee any protections.

viii. The proposal does not explain the real value of the federal property disclosure requirement of CERCLA 120(h)

The proposal does not explain whether there is any real value to the CERCLA federal property disclosure provision in CERCLA Section 120(h) that would be triggered by the designation of PFOA and PFOS as CERCLA hazardous substances. This kind of disclosure in the context of a sale of federal property and further cleanup commitment could be implemented by Executive Order directed to all federal agencies and by adoption of individual agency policies.

ix. The proposal identifies 5 broad categories of parties impacted, but neglects to identify the owners of property impacted by PFOA/PFOS

The proposal indicates five broad categories of parties impacted by the proposed regulation, but in a fundamental flaw fails to identify the largest group—property owners—for a contaminant that may be present everywhere in the United States. EPA cannot avoid considering the impact

of the proposed designation of PFOA and PFOS as CERCLA hazardous substances on the basis that EPA has no current plans to seek cost recovery against landowners. As explained above, the designation of PFOA and PFOS as CERCLA hazardous substances will automatically impose potential liability on current owners of property contaminated with PFOA and PFOS as well as those who owned property at the time PFOA and PFOS contaminated the property.

x. The proposal merely cities "meaningful" public health benefits without identifying what those benefits are and how they would be facilitated by the CERCLA designation

The proposal claims that the CERCLA designation will produce "meaningful" public health benefits but does not explain what those benefits would be or how CERCLA designation would create those benefits. While the proposal references significant progress in reducing PFOA and PFOS concentrations in blood levels of the general public[34] (which has corresponded with the ceasing of the manufacture and distribution of PFOA and PFOS), it does not explain how CERCLA designation will contribute to further reduction in blood levels. In fact, this proposal may cut against its intended goal in unexpected ways. For example, treating wastewater and drinking water to reduce or eliminate PFAS seems to be one of the approaches most likely to reduce background levels of PFAS contamination in the environment, providing the PFAS extracted from wastewater and drinking water can either be destroyed or managed in a permanent way. If the CERCLA designation of PFOA and PFOS makes it more expensive to treat wastewater and drinking water, it will ultimately slow down the treatment of water and the rate of removal of the background levels of PFAS. Unfortunately, this will require considerable resources and could equate to an additional tax on water. EPA's existing CERCLA removal authorities allows EPA to immediately address drinking water sources and reduce the acute risk of increased PFOA and PFOS exposure for the people using those sources of drinking water. Importantly, EPA has not articulated how CERCLA designation of PFOA and PFOS will compare or integrate with using other EPA authorities, such as the Clean Water Act and the Safe Drinking Water, to reduce background levels of exposure to PFOA and PFOS.

xi. EPA claims designation will have only limited direct economic impacts

On June 8, 2022, the U.S. Chamber of Commerce provided EPA with a detailed expert assessment of the potential costs of CERCLA hazardous substance designation.[35] This report provided considerable detail on the estimated costs to address PFOA and PFOS at existing non-federal national priority sites, which the report estimated could exceed $17 billion and have annual costs of between $700 million and $900 million.[36] Dr. Linda Birnbaum, recently retired but formerly a long time government scientist, recently published a study in *Environmental*

---

[34] *See e.g.* Proposed Preamble pages 54,417 and 54,427.
[35] *See*, the analysis prepared for US Chamber of Commerce, which is available at: https://www.uschamber.com/environment/pfos-and-pfoa-private-cleanup-costs-at-non-federal-superfund-sites. This analysis shows a mean estimate for existing NPL sites alone are present value $17.4 billion (90% prediction interval equaling $10 billion to $27.2 billion) using a 3% discount rate and $9.8 billion (90% prediction interval equaling $5.9 billion to $15 billion) using a 7% discount rate.
[36] *Ibid*

Science and Technology[37] that claims that there are over 57,000 presumptive contamination sites in the U.S. based on modeling conducted on "500 known sites."

EPA's initial claim that the CERCLA designation will have only limited direct economic impact was a position that OMB ultimately did not agree with as demonstrated by the change in the designation of the economic significance of the rule as it progressed through the interagency review process. Presumably this change of designation by OMB came about as OMB considered the information and evidence provided by various parties inside and outside of the government based on the 40 years of implementation of CERCLA. The change in designation towards the end of the inter-agency process may explain, in part, why EPA's evaluation of costs is so limited as it did not conduct a thorough cost analysis of the proposed rule prior to submitting it to OMB.

xii. The proposal incorrectly claims that cleanup costs and liability management are indirect effects

EPA's unwillingness to consider the reasonably expected range of costs does not mean the costs are indirect and not capable of assessment. The proposal does not analyze the DoD cost estimates based on DoD's considerable experience with PFOA and PFOS cleanups and overall CERCLA experience.[38] The clear intent of the rulemaking is to direct cleanups beyond what EPA thinks it can do with its existing authorities, which begs the question of why the costs of those cleanups is not considered a direct consequence of the rulemaking.

xiii. The Proposals Rationale Certifies that the Regulatory Flexibility Act (RFA) and the Small Business Regulatory Enforcement Fairness Act (SBREFA) do not apply

The proposal's handling of costs and the associated economic analysis fails to meet the statutory requirements, EPA's own economic guidance, Small Business Administration's (SBA) analysis of issues, and EPA's administration of CERCLA. The proposal fundamentally fails to adequately evaluate the costs notwithstanding having 40 years of CERCLA implementation experience and fails to assess the benefits for its proposal in comparison to the costs and benefits of not taking the proposed action.

As has been explained, the CERCLA designation of PFOA and PFOS as hazardous substances will have an impact on all landowners with PFOA and PFOS contamination, including farmers and ranchers, many of whom are small business owners. EPA cannot avoid the procedural requirements of these statutes by ignoring the impacts on farms, ranches, and many other small businesses. The SBA should conclude that the EPA's certification is improper and require EPA to conduct more evaluation of the cost impact of the proposed rule on small businesses. This could include: requiring EPA to conduct an Initial Regulatory Flexibility Analysis (IRFA) and

[37]Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources, *Environ. Sci. Technol. Lett.* 2022, Publication Date: October 12, 2022.

[38] *See, e.g.* Report on Per- and Polyfluoroalkyl Substances Active Sites Cleanup *Costs*, Office of the Under Secretary of Defense for Acquisition and Sustainment, June 2022.

take public comment on the analysis**;** convening panels of small entities to consider alternatives; and preparing an economic analysis consistent with Circular A- 4.

A closer look at the impact that EPA's proposal would have on small businesses would likely have demonstrated a significant potential adverse impact on farmers and ranchers. As discussed, these economic impacts are associated with CERCLA liability as landowners, added complications and additional costs associated with real estate transactions, and increased operational costs associated with limitations on the use of biosolids.

Farm Bureau Implores You to Consider Unintended Impacts on Agriculture

We appreciate the opportunity to bring light to the unintended consequences of this proposed rulemaking. Farmers all over the country could face devastating impacts simply for owning land and creating an agricultural product. PFAS contamination is a very serious issue, and we must work together to find solutions. However, families here at home and abroad are increasingly turning to America's farmers to provide for global food security. It is frightening to imagine a world where farmers are unable to produce the food, fuel and fiber that our country, and the world, relies on. For all of the reasons outlined in these comments, EPA must strongly consider these implications and should reevaluate moving forward with this proposal.

U.S. Chamber of Commerce

PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites

Prepared for the United States Chamber of Commerce
June 2022

U.S. Chamber of Commerce

Table of Contents

Executive Summary

The Environmental Protection Agency (EPA) is embarking on a costly and unnecessary rule-making with significant implications for businesses, consumers, and governments alike - the designation of certain Per-and polyfluoroalkyl substances (PFAS) as hazardous under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA). This report provides new analysis on the cost of cleanup for potentially responsible parties (PRP) for Perfluorooctanesulfonic acid (PFOS) and Perfluorooctanoic acid (PFOA), which total over $17.4 billion for existing non-federal national priority sites alone.

CERCLA authorizes the use of various enforcement tools to require PRPs such as private businesses, recycling and waste management companies, and governments to cleanup contaminated sites. EPA has some existing authority to address pollutants or contaminants like PFOA and PFOS found at existing CERCLA sites that present an imminent danger to the public health or welfare. Designating PFOS/PFOA as hazardous substances would create significant uncertainty regarding estimated cleanup costs for private entities. The uncertainty is driven in large part because designation would trigger new assessment and inspection, including sites with completed cleanups, and likely resulting in new NPL listings. The result is that PRPs at existing and new sites with PFOS/PFOA contamination would incur both direct cleanup costs and indirect transactional costs associated with the cleanup.[1]

The U.S. Chamber of Commerce engaged third party experts in environmental and economic modeling to estimate total private party costs for addressing PFOS/PFOA contamination at Superfund sites. CERCLA cleanup is already a complex process, and is further complicated by site specific variables, the inherent complexity of PFOS/PFOA, and EPA metrics guidance presently under review at the Agency.

These factors include:

- Difficulty in determining the scope of affected sites because PFOA/PFAS contamination remains mostly uncharacterized;
- Human health and environmental thresholds for PFOS/PFOA are not yet finalized by EPA;
- Specific NPL sites require remediation, but particular remedial actions are unknown and unclear because investigation has not yet begun;
- Size, complexity, and on-site specific factors such as the progress made in addressing the initial hazardous substance(s), and the overlap of PFOS/PFOA contamination; and
- A lack of clear PFOS/PFOA contamination goals for different cleanup pathways and receptors.

Additional uncertainty is created by pending and potential state-level action to regulate PFAS[2] and federal and state-level environmental agency action to update disposal polices that would increase cleanup costs. The decades-long process of CERCLA remediation makes it further challenging to estimate costs today, when many remediation phases will not be implemented for another five or more years. However, this complexity does not prevent a reasonable economic analysis now with the information available, as there are known economic impacts that will flow as a foreseeable consequence of a PFOS/PFOA listing.

In the past, EPA has asserted that the costs associated with designating PFOS/PFOA as hazardous would not have an annual effect, either costs or benefits, on the economy of $100 million, which is the threshold beyond which regulations are considered "economically significant" and subject to more thorough analysis and internal review. By not designating the rule as economically significant, the agency would be avoiding the responsibility of undertaking a formal regulatory impact analysis (RIA) of PFAS cleanup costs triggered by a CERCLA designation. This agency determination would be surprising given the potential for responsible private parties, not counting the federal government (particularly the Department of Defense (DoD)), to face major cleanup liabilities at a broad range of PFAS sites.

In order to ascertain a reasonable estimate of potential private cleanup costs triggered by a CERCLA designation, the Chamber's third-party experts conducted economic modeling and analysis of financial liabilities associated with cleanup of PFOS/PFOA sites. This research found:

- Private sector cleanup costs at Superfund sites alone resulting from the proposed hazardous substance designation of PFOA and PFOS are estimated to cost between $700 million and $800 million in annualized costs ($11.1 billion and $22 billion present value costs), far in excess of the $100 million annual effect threshold requiring an RIA.
- Private site cleanup costs are only one component of total costs that a CERCLA hazardous

substances designation would impose on the U.S. economy. Significant additional costs are expected to be incurred by (1) federal agencies that own and operate sites containing PFOS/PFOA, (2) municipalities responsible for community water systems, landfills, and publicly-owned treatment works, as well as at potential state and local brownfield sites. Additionally, beyond these direct cleanup costs to affected site owners that will likely be responsible for certain maintenance and operations programming, among others.

- While the Chamber acknowledges that estimating Superfund site cleanup costs is inherently uncertain, uncertainty has not prevented EPA from pursuing site cleanup and imposing these costs in the past.[3]

Figure 1: PFAS Remediation Timeline

	PA/SI	RI/FS	RD/RA	RA-O	LTM
	Preliminary Assessment/Site Inspection	Remedial Investigation/ Feasibility Study	Remedial Design/Remedial Action	Remedial Action Operations	Long Term Management
Years*	1-3	3-6	2-4	1-30+	1-30+

Private Party PFOS/PFOA Cleanup Cost are Estimated to be Between $700-800 million

To facilitate a critical review, the Chamber's third-party experts developed a probabilistic model projecting future PFOS/PFOA cleanup and transaction costs at non-federal Superfund sites[4] for private parties. The model assumes the assessment and inspection of 1,638 current, proposed, and former non-federal NPL sites and 538 new sites. Researchers used Monte Carlo methods to develop a probability distribution for total private party cleanup costs. Monte Carlo simulations are used to model the probability of different outcomes in a process that cannot be easily predicted due to the intervention of random variables. It is used to help explain the impact of risk and uncertainty in prediction and forecasting models. Considering only existing NPL sites, the mean cost estimate is present value $17.4 billion ($900 million annually) using a 3% discount rate and net present value $9.8 billion ($700 million annually) using a 7% discount rate. Assuming the CERCLA designation adds to the NPL 200 of the 538 new sites assessed, present value costs increase to $22 billion ($1.1 billion annually) and $11.1 billion ($800 million annually) at 3% and

Table 1: Private Sector PFOS/PFOA Cleanup Costs at NPL Sites, Mean Estimate

Billions of 2021 Dollars

Mean PCR Cost (N=10,000)	All NPL Sites	Existing NPL Sites	New NPL Sites
Present Value, 3% Discount Rate			
Total	$22.0	$17.4	$4.3
Annualized Cost Over 30 Years	$1.1	$0.9	$0.2
Present Value, 7% Discount Rate			
Total	$11.1	$9.8	$1.3
Annualized Cost Over 30 Years	$0.8	$0.7	$0.1

Notes: Existing NPL sites include final, proposed, and deleted NPL sites. Assumes the CERCLA designation adds 200 sites to the NPL.

Methods: Model and Assumptions

The Chamber's team modeled private party PFOS/PFOA cleanup costs using three inputs:

1. The number of non-federal NPL sites subject to each CERCLA cleanup phase,
2. The typical full cost for each CERCLA cleanup phase; and
3. The incremental cost that PRPs will incur to address PFOS/PFOA contamination at each CERCLA cleanup phase.

Multiplying these variables produces undiscounted cleanup costs. Undiscounted costs are costs expected to be generated or incurred, which have not been reduced to their present value. The model projects when each phase of cleanup will occur using typical durations for CERCLA cleanup phases. Future costs are then reduced to total and annualized present values using both 3% and 7% discount rates. The Monte Carlo simulation computes 10,000 iterations of the model by randomly selecting values from the probability distributions for the variables determining the present value of PFOS/PFOA cleanup costs, and the result is a probability distribution for total private sector cleanup costs.

The Chamber's team arrived at this top-down modeling construct, as a bottom-up approach was not feasible. That is because:

- Extrapolating PFOS/PFOA cleanup costs from representative sites to all NPL sites would require previously completed cleanup data, and
- The lack of site-specific cost outcomes required the Chamber to develop probability distributions from judgments formed using data points from government sources, input from the regulated community, and input from the environmental consulting industry.

The following sub-sections explain the model inputs, assumptions, and data. A discussion of the model's results and their uncertainty follows in the nextsection.

PFOS/PFOA CERCLA Cleanup Phases for NPL Sites

1. When determining whether a site should be added to the NPL, EPA utilizes information from initial limited investigations in the Preliminary Assessment and Site Inspection (PA/SI) process to assess the potential threat to human health or the environment through the Hazard Ranking System (HRS).
2. Following an NPL listing, the site undergoes a robust Remedial Investigation and Feasibility Study (RI/FS) to determine the nature and extent of contamination at the site, test whether certain technologies can treat the contamination, and evaluate the cost and technologies that could be used to clean up its Operable Units (OUs).
3. This information informs the design and implementation of remedial action from the record of decision (ROD) during the Remedial Design and Remedial Action (RD/RA) phase.
4. Remedial actions involving groundwater or surface water require long-term monitoring and operation that EPA classifies as the Long-Term Remedial Action (LTRA) phase.

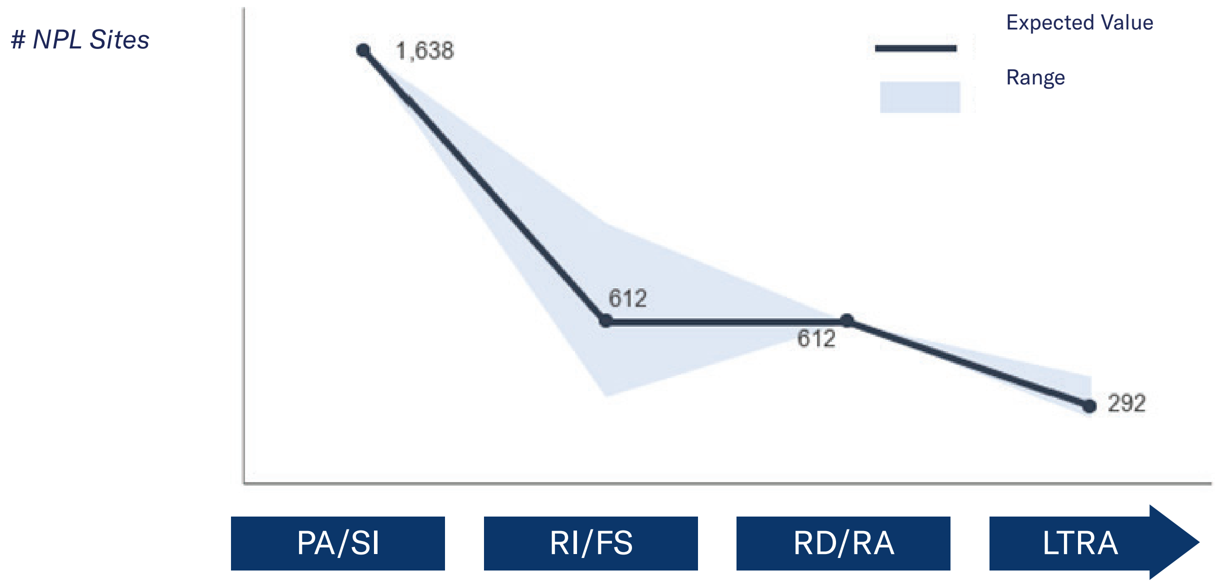
Chamber modeling assumes that EPA will require all existing non-federal NPL sites to look for PFOS/PFOA contamination through a PA/SI process. Existing NPL sites comprise the 1,638 reported in EPA's Superfund Program Superfund Public User Database LIST-008R Active Site Status Report All Action Types:

- 1,164 sites on the final NPL,
- 48 sites proposed for the final NPL, and
- 426 sites deleted from the NPL that a CERCLA designation could "reopen."

The model conservatively excluded the 335 non-federal sites that EPA identifies as "Part of an NPL site."[5] Even so, the number of sites that must be assessed and inspected for PFOS/PFOA contamination is highly uncertain. To date, EPA has identified fewer than 200 non-federal NPL sites with known or suspected PFOS/PFOA releases subsequently discussed. While we discuss the impact of this uncertainty for our cleanup cost estimates, the Chamber is confident that EPA will seek widespread assessments at existing NPL Sites.

This analysis projects the proportion of existing NPL sites advancing to each subsequent CERCLA cleanup phase using the probability distributions and their bases described in Appendix A. Use of probability

Figure 2: Existing NPL Sites at Each Phase of PFOS/PFOA CERCLA Cleanup



Notes: Preliminary Assessment / Site Inspection (PA/SI). Remedial Investigation / Feasibility Study (RI/FS). Remedial Design / Remedial Action (RD/RA). Long-Term Remedial Action (LTRA).

PA/SI-to-RI/FS:	Of the 1,638 existing NPL sites requiring PA/SI, 612 (37%) advance to the RI/FS phase within range of 328 to 983 (20% to 60%).
RI/FS-to-RD/RA:	All of the 612 existing NPL sites requiring RI/FS would require remedial action and advance to the RD/RA phase.
RD/RA-to-LTRA:	Of the 612 existing NPL sites requiring remediation, 292 (48%) require long-term treatment and monitoring of groundwater or surface water within a range of 244 to 408 (40% to 67%).

distributions intends to capture and illustrate the uncertainty for advancement rates from the absence of PFOS/PFOA Hazard Ranking System (HRS) scores for the universe of NPL sites, RI/FS outcomes, and RODs identifying sites with OUs requiring remediation and identifying the action(s) to be taken.

The Chamber's experts make the conservative assumption that PFOS/PFOA contamination will add 20 sites annually to the NPL over the next decade, for a total of 200 sites requiring RI/FS and subsequent remediation. This assumption is based off of EPA's average NPL listing rate from FY1998 through FY2007.[6] Using the same expected advancement rates and probability distributions as the existing NPL sites implies that 536 new sites would require PA/SI, and that 96 of the 200 new sites could expect LTRA.

The assumption that PFOS/PFOA adds only 200 new NPL sites is highly conservative. Using publicly available EPA data, the Chamber's expert research identified approximately 44,000 sites nationwide as "may be handling PFAS" that are neither existing NPL sites nor in the RCRA program, either as hazardous waste generators or as permitted treatment, storage, or disposal (TSD) facilities.[7] State PFAS cleanup programs will address an uncertain but not insignificant proportion of these sites. For example, as of 2002 there were 50 known or suspected contaminated state sites for every site on the final NPL, and 20 state sites needing attention for every NPL site.[8] Notably, the dataset identifies approximately 4,000 landfills, which are the most likely candidates for addition to the NPL.[9]

Cost of PFOS/PFOA CERCLA Cleanup

The model projects PFOS/PFOA cleanup costs as a percentage of (i.e., an increment to) the typical full cost that PRPs incur for each cleanup phase. An explanation of the data, assumptions, and distributions for typical full phase costs and incremental costs for PFOS/PFOA are reported in the following table. Appendix B provides backup data and supporting calculations.

The Chamber's experts obtained typical costs from EPA and Government Accountability Office (GAO) sources to complement its own data and research. EPA reported typical costs per OU at non-federal sites in its 2005 publication Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition. It provides costs in 2003

dollars for all phases except PA/SI. Costs are adjusted for inflation to 2021 using the GDP implicit price deflator. The model constructs site-level cleanup phase costs from the OU-level at the average of three OUs per NPL site. The DoD's PFAS response provides data to derive a PA/SI cost per site. Monte Carlo iterations sample typical costs from log-normal distributions constructed using standard deviations of 10%, 15%, or 25% of the mean, depending on the phase.

Typical costs for each cleanup phase are representative if addressing PFOS/PFOA contamination will constitute “starting over” at the site. While plausible under certain circumstances, PFOS/PFOA cleanup costs will, more likely than not, be incremental. For example, members of the regulated community have stated that a new PA/SI could easily amount to 30% of the initial cost. The degree to which PFOS/PFOA costs are incremental depend largely on uncertain factors. Some are site specific, such as the extent of overlap of contamination pathways and plumes of initial contaminants of concern (COC). Others are global, such as developing remediation goals protective of human health and the environment, which may also lead to other EPA regulatory actions (e.g., the SDWA). The next section discusses these and other uncertainties for determining incremental costs.

Although cleanup costs generally increase with the number of COCs at a site, that cost differential is not useful for modeling the incremental cost impact of a COC listed during or after the cleanup process as will be the case for existing NPL sites. The Chamber developed PERT probability distributions[10] for incremental cost impacts from conversations with the regulated community, its own research, and input from environmental consultants. Ranges and central tendencies of the distributions vary across phases and the cleanup status to illustrate the uncertainties for addressing PFOS/PFOA contamination at existing NPL sites.[11] The model adds a 10% to 50% (distributed uniformly) cost increment for new NPL sites to reflect that PFOS/PFOA cleanup costs will be closer to full cost than at existing NPL sites.[12]

PRPs also incur significant transaction costs throughout the CERCLA cleanup process. These can include legal and consultant fees for support through cleanup processes, and for litigation seeking cost recovery, contribution, and indemnification from other parties and insurance companies. According to a RAND Corporation study that EPA supported, transaction costs amount to nearly half of the investigation and remediation (IR) costs. The model samples the transaction cost ratio from a uniform distribution to compute the dollar amount from the sampled PFOS/PFOA IR costs for each Monte Carlo iteration.

Table 2: Typical PRP Costs for CERCLA Cleanup and Incremental Cost to Address PFOS/PFOA

PRP Cost Category	Cost Distributions Used in the Monte Carlo Model		
	Typical Cost, Mean (SD) 2021$M / Site	PFOS/PFOA Cost Increment (% of Typical)	
		Existing Sites	New Sites
CERCLA Cleanup Phase			
PA/SI	Log-normal(3.4, 0.3)	PERT(20%, 33%, 50%)	+Uniform(10%, 50%) of Existing Sites
RI/FS	Log-normal(6.0, 0.6)		
RD	Log-normal(6.0, 0.9)	PERT(5%, 33%, 50%)	
RA, Not stated/WIP	Log-normal(51.1, 12.8)	PERT(5%, 33%, 67%)	
RA, Completed		PERT(5%, 50%,100%)	
LTRA	Log-normal(44.3, 6.6)	PERT(5%, 33%, 67%)	
Transaction Cost	Mean = 28.7, s.d. = 4.8	Uniform(36%, 54%)	

Notes: Typical costs and for CERCLA cleanup phases follow a log-normal distribution (mean, standard deviation). "SD" abbreviates standard deviation. PFOS/PFOA cost increments for CERCLA cleanup phases follow a PERT distribution (minimum, mode, maximum). Transaction costs are computed as 45% of the total investigation and remediation (IR) costs (RI/FS, RD, and RA) and are sampled from a uniform distribution (minimum, maximum). WIP is Work-in-Progress, EPA reports 62% of the 1,164 sites currently on the NPL as Construction Complete.

Projecting PFOS/PFOA Cleanup Timelines

As PFOS/PFOA cleanup under CERCLA unfolds over the next several years, PRPs will incur costs in the future. Future cost streams are reduced to a present value at both 3% and 7% discount rates consistent with the Office of Management and Budget's (OMB) guidance to agencies on good regulatory analysis in OMB Circular A-4. Annualized equivalent costs are computed for a 30-year policy period.

The model uses GAO data for the average time-to-complete CERCLA cleanup phases to project when PRPs will incur costs at existing NPL sites. As the following table shows, cleanup at new sites will occur further into the future than cleanup at existing sites. This reflects both that EPA would add NPL sites gradually over the decade spanning from 2024 to 2033, and that new sites would have less infrastructure in place to leverage. The projection and thus the present value calculation assume that all sites must complete one phase before beginning the next.

Discussion: Results and Uncertainties

The results show that annualized costs would have annual economic effects greater than $100 million that necessitates the development of a regulatory impact analysis and should also be designated as "major" under the Congressional Review Act, the Unfunded Mandates Reform Act, and Executive Order 12866.[13] The cost estimate exceeds $100 million annually even at the lower fifth percentile of the cost distribution, considering just the impacts at existing NPL sites, and at both a 3% and 7% discount rate. Unsurprisingly, the remedial action costs exhibit the highest degree of uncertainty in both dollars and percentage terms. That is due to the difference in incremental costs between sites where the remedial action is complete and at those that require long-term treatment of groundwater and surface water. The subsections that follow include a wider discussion of uncertainties, including from changing maintained assumptions and the uncertainties implicitly captured through the model's illustrative probability distributions.

Table 3: Projected Timing of PFOS/PFOA CERCLA Cleanup for Determining Present Values for Estimated Cleanup Costs

CERCLA Cleanup Phase	Years When Cleanup Occurs	
	Existing NPL Sites	New NPL Sites
PA/SI	2024–2027 (4 years)	2024–2043 (20 years)
RI/FS through RD	2028–2036 (9 years)	2044–2062 (19 years)
RA	2037–2038 (2 years)	2063–2073 (11 years)
LTRA	2039–2068 (30 years)	2074–2104 (30 years)

Notes: Numbers in parentheses are durations for the CERCLA phase.

Table 4: Results of Monte Carlo Model Simulating PRP CERCLA Response and Cleanup Costs for PFOS/PFOA

N = 10,000	All Sites with PFOS/PFOA			Existing NPL Sites			New NPL Sites		
	Mean	90% PI		Mean	90% PI		Mean	90% P1	
Present Value Costs, Billions of 2021 Dollars									
<u>Present Value. Discounted at 3%</u>									
Total NVP of PRP Costs	$22.0	$13.8	$32.6	$17.4	$10.0	$27.2	$4.3	$2.8	$6.0
Annualized Cost Over 30 Years	$1.1	$0.7	$1.7	$0.9	$0.5	$1.4	$0.2	$0.1	$0.3
Present Value. Discounted at 7%									
Total NVP of PRP Costs	$11.1	$7.1	$16.3	$9.8	$5.9	$15.0	$1.3	$0.8	$1.8
Annualized Cost Over 30 Years	$0.8	$0.5	$1.2	$0.7	$0.4	$1.1	$0.1	$0.1	$0.1

Notes: PI abbreviates prediction interval.

Alternative Model Construct

The Chamber's top-down model construct is illustrative, and it does not use site-specific information. However, extrapolating from representative sites can be challenging because costs may vary across sites unsystematically. Prohibiting the representative site approach in this case is the complete absence of representative PFOS/PFOA cleanups.

Model Limitations: Number of Sites Affected

An uncertainty that the Monte Carlo does not quantify is the true number of NPL sites that EPA ultimately requires to assess and inspect for PFOS/PFOA. The model assumes that all 1,638 NPL sites conduct a PA/SI to ensure PFAS are not present. However, the current CERCLA designation is limited to PFOS/PFOA, and two EPA sources suggest there are fewer than 200 non-federal NPL sites where contamination is known or suspected[14]. As the following table shows, the number of sites requiring PA/SI may be a significant uncertainty for the total cost estimate.

The number of sites advancing to RI/FS is uncertain absent the HRS scoring process for existing and potential NPL sites. The model assumes that private NPL sites advance to RI/FS at the same rate (36%) as the more than 250 sites where DoD has responded to PFAS contamination. That assumption may over-advance private sites because virtually all DoD sites have PFOS contamination from aqueous firefighting foam (AFFF) use. It may under-advance private sites pending EPA promulgating a national drinking water standard for PFOS/PFOA more stringent than the 70 nanograms per liter (ng/L) lifetime health advisory to which DoD has responded thus far. Furthermore, PFAS have demonstrated migration through all four HRS pathways.

To illustrate the uncertainty, each Monte Carlo iteration samples advancement rates from a PERT distribution ranging from 20% to 60%. Chamber experts developed the range from State of New Hampshire data and other state PFAS investigation data. As the following table shows, varying the RI/FS advancement rate increases or decreases the baseline cost estimate by approximately 30%.

Table 5: Sensitivity of PFOS/PFOA CERCLA Cleanup Cost Estimates to Selected Inputs

Estimate	Existing NPL Sites Requiring PA/SI	% Advancing to RI/FS	**Mean Value, Billions** Present Value, 3%	Change from Baseline
Baseline (Model)	1,638	36%	$17.4	$0.0
Sensitivity 1	212	36%	$1.5	($15.9)
Sensitivity 2	1,638	20%	$8.4	($9.0)
Sensitivity 3	1,638	60%	$15.2	($2.2)

Size, Complexity, and Type of Affected Site

Each Monte Carlo iteration uses a Superfund Site with three Operable Units (OUs) to aggregate from EPA's typical CERCLA cleanup phase costs for an OU. The 1,638 existing NPL sites average three OUs and range from one to ten. Variation from the average Superfund site size in this model construct is due to the fact that some areas that require PFOS/PFOA investigation and remediation are systematically larger or smaller than the average site.[15] There are no data available for making that determination, thus the model uses the average OUs per site.

Even so, the number of OUs may not adequately reflect a site's area. For example, the contaminated sediment sites along industrial waterways are larger in area than landfill, recycling, and manufacturing Superfund sites, yet both have the same average number of OUs.[16] These contaminated sediment sites have hundreds of parcels and PRPs, which can significantly increase transaction costs relative to actual cleanup costs.

Current EPA cleanup cost data prevents varying costs by contamination pathway (e.g., groundwater, wetlands, sediment) or the nature of the site (e.g., landfill, cement manufacturing, waste handling, mining). Both variables can influence cleanup costs, and thus the incremental PFOS/PFOA costs in the model. Further, it is unclear whether current EPA cleanup and transaction cost data the model uses represent a complex contaminated sediment site, because both EPA data studies pre-date cleanup phases for several contaminated sediment sites.

Factors Affecting Incremental Costs

Determining the degree to which PFOS/PFOA cleanup costs are incremental depends on the degree of overlap with the initial contaminants of concern (COCs) at the site. The overlap can be described by several factors, none of which the model explicitly quantifies in the absence of available data. These are:

- The degree of overlap in contamination pathways and contaminated areas within and across OUs–depending on the site type and use of PFAS, the releases (e.g., sites with AFFF releases only) may constitute an entirely new OU;
- The degree to which the remediation goals overlap in terms of pathways, receptors, and endpoints;
- The degree to which remediation technologies capable of achieving respective remediation goals overlap;
- The existence and extent of administrative, technical, and physical infrastructure developed through cleanup of the initial COC that PFOS/PFOA cleanup can leverage to achieve cost economies of scope;
- The site's progress in the cleanup of the initial COCs—it is one thing to add a COC to the beginning of the RI/FS phase, and quite another once the ROD is issued; and
- The adequacy of remedial actions designed or installed for initial COCs to achieve PFOS/PFOA remediation goals, among others.

Although the model does not explicitly quantify these uncertainties, the probability distributions for the incremental PFOS/PFOA cost are designed to implicitly capture such uncertainties through the cost distributions generated by the model. Following are additional uncertainties that could uniquely influence PFOS/PFOA cleanup costs.

SDWA Compliance

The outcome of EPA's regulation of PFOS/PFOA under the Safe Drinking Water Act (SDWA) introduces uncertainty because Superfund site cleanups would have to meet its maximum contaminant levels (MCLs). Much of the focus to date has been on EPA's 70 ng/L lifetime health advisory, whereas EPA's draft reference dose limits are near zero.[17] It is unclear whether and how typical remedial action costs used in the model would increase if all affected sites had to achieve non-detectable PFAS concentrations in groundwater and surface water sources that are used or could be used as drinking water sources. The affected sites, which could conceivably include any sites with groundwater or surface water pathways, would require larger treatment systems and/or longer-term and more frequent operations and management (O&M), the extent of which depends on source concentrations, among other technical variables.

PFAS End-of-Life Restrictions

Several potential and future requirements, including provisions in the FY 2020 National Defense Authorization Act (NDAA) and pending other legislation, would direct EPA's Administrator to promulgate regulations addressing incineration of PFAS waste. Restricting or banning PFAS waste incineration and thermal treatment methods would further raise the cost of Superfund site cleanups. PRPs with access can thermally treat PFAS-contaminated soil, rendering it non-hazardous for reuse onsite or for disposal via a municipal solid waste (MSW) landfill.[18] An analysis by the Chamber shows that prohibiting thermal treatment of PFAS contaminated soil would raise costs at a single NPL site by up to $1 million and that approximately 25% of the existing NPL sites would find onsite incineration more cost effective than disposal at a Subtitle C landfill (see Appendix C).

Ecological Remediation Goals

Much of the focus on PFAS cleanup has centered around drinking water. However, cleanups required to meet future ecological remediation goals could result in even greater costs. California, for example, proposed PFAS ecological screening levels in aquatic habitats below instrument detection capabilities.[19] Despite the absence of site characterizations, the Chamber's analysis of California NPL sites and the U.S. Fish and Wildlife Service National Wetlands Inventory suggests that ecological remediation requirements could be significant. Of the 90 non-federal NPL sites in California, 63 (70%) had at least one wetland within a half mile. That may be a significant statistic when

considering PFAS' low retardation rate and the recent evidence suggesting aerial pathways from stack emissions at manufacturing facilities.

Factors Affecting the Timing of Future Cleanup

Projecting future CERCLA cleanup timelines is another uncertainty because several unobservable factors can affect the progress of any one site. These can include the nature and extent of public involvement, the course and complexity of litigation among the PRPs or with other parties, EPA enforcement staff availability and funding levels, and absence of PRPs or significant orphan cost shares, among others. Although the GAO provided average durations for the various CERCLA phases, detailed data on OU statuses at NPL sites suggests time-to-complete phases varies widely among sites. Early investigations have uncovered PFAS substances other than PFOS/PFOA, which is likely to lengthen cleanup times. That would surely delay cleanup and lower present value costs. However, without a basis for quantifying the additional time, the Chamber used average cleanup phase durations that GAO developed from EPA's data.

Conclusion and Recommendations

The results of the model illustrate the likely significant cost of PFOS/PFOA cleanup at non-federal Superfund sites. However, there is some uncertainty around the model's estimates. A top down modeling approach was used in the absence of site-specific data due to the fact that PFOS/PFOA are not currently designated as hazardous substances under CERCLA, and that no sites have completed cleanups. It is the Chamber's view that EPA should develop simulated PFOS/PFOA cleanup costs for existing NPL sites for the regulated community's review and input. Regardless, the Chamber's Monte Carlo model illustrates that PRP costs for PFOS/PFOA cleanup will be significant. Mean estimates for existing NPL sites alone are present value $17.4 billion (90% prediction interval equaling $10 billion to $27.2 billion) using a 3% discount rate and $9.8 billion (90% prediction interval equaling $5.9 billion to $15 billion) using a 7% discount rate. Uncertainty in these estimates notwithstanding, CERCLA cleanup costs are but a single component of total costs, which include long-term operations and maintenance programming and monitoring, that the CERCLA designation for PFOS/PFOA imposes on the private sector and communities across the nation. Prior to proposing any designation, EPA should comply with its statutory and Executive Order requirements to conduct a cost-benefit analysis of the proposed action and possible alternatives.

The Chamber and our members encourage EPA to develop simulated PFOS/PFOA cleanups for a set of existing NPL sites with different attributes that influence costs.[20] EPA's simulation should consider the effectiveness of alternative cleanup technologies and the implications of future regulation and policy relating to PFAS waste management and disposal.

Endnotes

1. EPA's indirect costs cover the costs of administering the Superfund program that cannot be attributable to any specific site.
2. Another factor with the potential to significantly affect incremental costs for addressing PFOS/PFOA are cleanup standards being enacted by many states and the interaction between those state standards and CERCLA. Section 121 of CERCLA and EPA's National Contingency Plan regulations allow EPA to use state standards as "Applicable or Relevant and Appropriate Requirement" (ARARs) to set federal preliminary remediation goals for site cleanup.
3. For example, the EPA estimated the cost of cleanup at 456 non-federal NPL sites comprising 1,073 operable units (OUs) with planned remedial actions at between $15.5 and $23.3 billion in 2003 dollars (see the EPA Office of Solid Waste and Emergency Response, Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition. the EPA 542-R-04-015. 2005). In the same study, the EPA uses a similar approach to the Chamber's model to project future CERCLA cleanup costs and derives a range from $23billion to $50billion. The study makes key assumptions in the absence of available data; for example, "It was assumed that 50 percent of sites with RD underway have already incurred the RD costs, 50 percent of sites with study underway already have incurred RI/FS costs, and 45 percent of all sites will require LTRA."
4. Non-federal Superfund sites
5. U.S. EPA, Superfund Program Superfund Public User Database LIST-008R Active Site Status Report All Action Types, Run Date: November 11, 2021. https://www.epa.gov/superfund/superfund-data-and-reports.
6. U.S. GAO, Litigation Has Decreased and the EPA Needs Better Information on Site Cleanup and Cost Issues to Estimate Future Program Funding Requirements, GAO-09-656, July 2009.
7. Also excluded are sites the EPA classified as "Oil and Gas", "Petroleum", or "National Defense".
8. Environmental Law Institute (ELI), An Analysis of State Superfund Programs, 50-State Study, 2001 Update. Nov. 2002.
9. These are facilities the EPA classified as "Waste Management" with "Landfill" in the facility name.
10. PERT distributions are widely employed in risk analysis because the distribution is useful in circumstances of limited information, as it requires estimating the upper and lower bounds and the most likely value.
11. For example, if the remedial action is designed but not complete, there is an ability to augment it to address PFOS/PFOA contamination. That is not the case if the remedial action is complete. For that reason, the maximum incremental RA cost is 100% (i.e., starting over) for sites with completed remedial actions and 67% for sites where the remedial action is not complete.
12. Although PFOS/PFOA would be responsible for the new sites' addition to the NPL, cleanup of other COCs may leave administrative, technical, or physical infrastructure to leverage in addressing PFOS/PFOA contamination.
13. EO 12866, Congressional Review Act, and UMRA all impose additional cost-benefit analysis requirements on agencies when the costs (or benefits) are greater than $100 million/year.
14. Approximately 90 of the 180 sites identified by the EPA to have PFAS contamination appear to be non-federal. https://www.epw.senate.gov/public/index.cfm/superfund-sites-identified-by-epa-to-have-pfas-contamination. As of June 2020, the EPA had identified 233 private and federal facility NPL sites with PFOS and PFOA contamination. The document does not provide a breakdown between private and federal sites. https://www.epa.gov/sites/default/files/2021-01/documents/frl-10019-13-olem_addressing_pfoa_pfos_anprm_20210113_admin-508.pdf
15. Varying the number of OUs for each iteration introduces false uncertainty because extreme values are generated when all Superfund sites are very large (e.g., 8 OUs) or very small (e.g., 1 OU).
16. See the EPA Large Sediment Sites Tiers 1 and 2 (https://www.epa.gov/sites/default/files/2015-10/tier1_sites_forwebsite_july-2015.xls)
17. See the EPA's Analyses to support the EPA's National Primary Drinking Water Rulemaking for PFAS.
18. According to the EPA data, 8% of Superfund remedial actions use thermal treatment and another 17% use offsite or onsite incineration.
19. See https://www.waterboards.ca.gov/rwqcb2/water_issues/programs/ESL/PFAS_ESL_Memo.pdf
20. For example, site type, size, pathways, media, number, and type of initial COCs, degree of overlap with initial COCs, geographic locations, proximate environmental and human receptors, PFOS/PFOA concentrations, preliminary remediation goals.

References

- Bagenstose, Kyle. “Navy Official: ‘Probably’ no more removal of PFAS-contaminated soil. The Intelligencer. June 6, 2019. https://www.horshamwater-sewer.com/sites/default/files/6.6.19_navy_official_probably_no_more_removal_of_pfas-contaminated_soil.pdf
- Bureau of Economic Analysis (BEA), GDP Implicit Price Deflator, via Federal Reserve Board of St. Louis Economic Data (FRED), https://fred.stlouisfed.org/series/GDPDEF#0
- Circular A-4. September 17, 2003, https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/. Accessed January 2022.
- DPRA Incorporated. Unit Cost Compendium. Data & Algorithms for Estimating Costs Associated With “Cradle-to-Grave” Management of RCRA Solid and Hazardous Wastes. Prepared for US Environmental Protection Agency Office of Solid Waste Economics, Methods & Risk Analysis Division. September 30, 2000. https://ertpvu.org/RCRA/Documents/Financial%20Assurance/Unit%20Cost%20Compendium-EPA-HQ-RCRA-2002-0031-0429.pdf
- ECHO Exporter. Downloaded October 21, 2021
- Environmental Law Institute (ELI). An Analysis of State Superfund Programs, 50-State Study, 2001 Update. November 2002. https://www.eli.org/research-report/analysis-state-superfund-programs-50-state-study-2001-update
- Guide to Regulated Facilities in ECHO, Resource Conservation and Recovery Act (RCRA) Designations. Available at: https://echo.epa.gov/resources/guidance-policy/guide-to-regulated-facilities. Last Updated July 2016. Accessed December 2021.
- Lloyd S. Dixon, Deborah S. Drezner, James K. Hammitt (RAND). Private-Sector Cleanup Expenditures and Transaction Costs at 18 Superfund Sites. 1991.
- Lloyd S. Dixon, Deborah S. Drezner, James K. Hammitt. Private-Sector Cleanup Expenditures and Transaction Costs at 18 Superfund Sites. RAND Corporation. 1991.
- Map of Commercial Waste Combustors in the U.S. EPA. https://www.epa.gov/hwgenerators/map-commercial-waste-combustors-us. Accessed: November 2021.
- Naugle, Alec. Transmittal of Interim Final Environmental Screening Levels (ESLs) for Two Per- and Polyfluoroalkyl Substances (PFAS): Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoate (PFOA), San Francisco Bay Regional Water Quality Control Board, California Water Boards, May 27, 2020, https://www.waterboards.ca.gov/rwqcb2/water_issues/programs/ESL/PFAS_ESL_Memo.pdf
- PFAS Map | EPA Identifies More Than 120,000 Potential PFAS Sites in U.S., Public Employees for Environmental Responsibility (PEER). https://www.peer.org/areas-of-work/public-health/pfas/pfas-map/
- RCRAInfo. Downloaded November 30, 2021
- State of New Hampshire Department of Environmental Services (NHDES). Statewide PFAS Occurrence Status Report, June 2021. https://www4.des.state.nh.us/nh-pfas-investigation/wp-content/uploads/Statewide-PFAS-Occurrence-Status-Report.June_.2021.pdf
- U.S. Environmental Protection Agency (EPA), Large Sediment Sites Tiers 1 and 2, https://www.epa.gov/sites/default/files/2015-10/tier1_sites_forwebsite_july-2015.xls, Downloaded March 2022.
- U.S. EPA Science Advisory Board. 2021. Analyses to support EPA's National Primary Drinking Water Rulemaking for PFAS, 1) PDF for Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water, 2) PDF for Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water, https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601
- U.S. EPA. Search Superfund Site Information, https://cumulis.epa.gov/supercpad/cursites/srchsites.cfm
- U.S. EPA. Superfund Program Superfund Public User Database LIST-008R Active Site Status Report All Action Types, Run Date: November 11, 2021. https://www.epa.gov/superfund/superfund-data-and-reports.
- U.S. EPA. Cleaning Up the Nation’s Waste Sites: Markets and Technology Trends: 2004 Edition. EPA 542-R-04-015. 2005. https://nepis.epa.gov/Exe/ZyPDF.cgi/30006II3.PDF?Dockey=30006II3.PDF.

- U.S. EPA. Data Downloads https://echo.epa.gov/tools/data-downloads
- U.S. EPA. Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances. Interim Guidance for Public Comment. December 18, 2020. https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not
- U.S. Fish and Wildlife Service, National Wetlands Inventory data. https://www.fws.gov/node/264586
- U.S. GAO. Litigation Has Decreased and EPA Needs Better Information on Site Cleanup and Cost Issues to Estimate Future Program Funding Requirements, GAO-09-656, July 2009.
- U.S. GAO. Times to Complete Site Listing and Cleanup, Statement of Peter F. Guerrero. Director, Environmental Protection Issues, Resources, Community, and Economic Development Division. GAO/T-RCED-98-74. 1998.
- U.S. Government Accountability Office (GAO). DoD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information. GAO-21-421. 2021.
- United States Senate Committee on Environment and Public Works, Superfund Sites Identified by EPA to Have PFAS Contamination, https://www.epw.senate.gov/public/index.cfm/superfund-sites-identified-by-epa-to-have-pfas-contamination
- Wheeler, Andrew. Advanced Notice of Preliminary Rulemaking (ANPRM): Addressing PFOA and PFOS in the Environment: Potential Future Regulation Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act, 6560-50-P. January 14, 2021, https://www.epa.gov/sites/default/files/2021-01/documents/frl-10019-13-olem_addressing_pfoa_pfos_anprm_20210113_admin-508.pdf

Appendix A. Monte Carlo Model Parameters

Parameter	Units	Value	Basis
Advancement Rates to CERCLA Phases			
Sites Advanced to RI/FS	% of PA/SI Sites	PERT(20%, 36%, 60%)	GAO 21-421 (see Appendix B)
Sites Requiring RD/RA	% of RI/FS Sites	100%	Assumed, as consistent with EPA practice.
NPL Sites with Completed RA	% of RD/RA Sites	62%	Computed from EPA LIST-008R
Sites Requiring LTRA	% of RD/RA Sites	PERT(40%, 45%, 67%)	Model value uses EPA (2005), p.3-14
Typical CERCLA Cleanup and Indirect Costs			
PA/SI	$M / Site	Log-normal(3.4, 0.3)	GAO-21-421 (see Appendix B)
RI/FS	$M / Site	Log-normal(6.0, 0.6)	EPA (2005), p.3-13 (see Appendix B)
RD	$M / Site	Log-normal(6.0, 0.9)	
RA	$M / Site	Log-normal(51.1, 12.8)	
LTRA	$M / Site	Log-normal(44.3, 6.6)	
Transaction Cost	% of IR Cost	Uniform(36%, 54%)	RAND (1993) (see Appendix B)
PFOS/PFOA Cleanup Cost Increment			
PA/SI	% of Typical Cost	PERT(20%, 33%, 50%)	Assumed
RI/FS	% of Typical Cost	PERT(20%, 33%, 50%)	Assumed
RD	% of Typical Cost	PERT(5%, 33%, 50%)	Assumed
RA, Not Complete	% of Typical Cost	PERT(5%, 33%, 67%)	Assumed
RA, Construction Complete	% of Typical Cost	PERT(5%, 50%,100%)	Assumed
LTRA	% of Typical Cost	PERT(5%, 33%, 67%)	Assumed
Other Parameters			
Operable Units	# / Site	3	EPA Search Superfund Site Information and EPA's LIST-008R
Cleanup (i.e., Policy) Duration	# Years	50	Assumed
Discount Rate, low	%	3	Circular A-4
Discount Rate, high	%	7	Circular A-4

Notes: Distributions are: Log-normal (mean, standard deviation), PERT (minimum, mode, maximum), and Uniform (minimum, maximum). Investigation and remediation (IR) costs equal the sum of RI/FS, RD, and RA.

Appendix B. Cleanup Cost Data

Typical CERCLA Cleanup Costs and Associated Transaction Costs Used as the Basis for Incremental PFOS/PFOA Cleanup Costs

Millions of 2021 Dollars

PRP Cleanup Costs	$ / OU	$ Site
Preliminary Assessment / Site Inspection (PA / SI)	1.1	3.4
Remedial Investigation / Feasibility Study (RI / FS)	2.0	6.0
Remedial Design (RD)	2.0	6.0
Remedial Action (RA)	17.0	51.1
Transaction Costs	9.6	28.7
Total, Sites without Long-term Remedial Action (LTRA)	31.8	95.3
Long-Term Remedial Action (LTRA)	14.8	44.3
Total, Sites Requiring LTRA of Groundwater or Surface Water	46.5	139.5

Notes: Site-level cleanup costs for all but the PA / SI phase (note a) and Transaction Costs (note b) are EPA averages per operable unit (OU) and 3 OUs per site. OUs per site is the average from the 1,638 existing NPL sites. Primary sources for private party cleanup costs are USEPA (2005), GA0-21-421, and RAND (1993). Costs stated in 2003 dollars are inflation-adjusted to 2021 dollars using the GDP Implicit Price Deflator, the same deflator EPA (2005) used.

[a] GAO-21-421 reports total expenditures and the number of sites. The cost per OU displayed here uses the 3 OU per site average.

[b] Computed as 45% of investigation and remediation cost (IR) based on RAND (1993). IR costs are the total of RI / FS, RD, and RA cost.

Typical CERCLA Cleanup Costs per Operable Unit Adjusted for Inflation to 2021 Dollars

Millions of 2021 Dollars

CERCLA Cleanup Phase	Cost per OU, 2003	Cost per OU, 2021
Remedial Investigation / Feasibility Study (RI / FS)	1.4	2.0
Remedial Design (RD)	1.4	2.0
Remedial Action (RA)	11.9	17.0
Subtotal before Long-term Remedial Action (LTRA)		21.1
Long-Term Remedial Action (LTRA)	10.3	14.8
Total Including LTRA		35.8

Notes: Source is EPA (2005), Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition, EPA 542-R-04-015, p.1-7, https://nepis.epa.gov/Exe/ZyPDF.cgi/30006113.PDF?Dockey=30006113.PDF. The Long-Term Remedial Action phase for "sites that require long-term treatment to restore groundwater or surface water." Costs stated in 2003 dollars are inflation-adjusted to 2021 dollars using the GDP Implicit Price Deflator (https://fred.stlouisfed.org/series/GDPDEF#0), the same deflator USEPA (2005) used.

PRP Transaction Costs for Investigaton and Remediation of Superfund Sites

Millions of 2021 Dollars

Cost Element	90% CI		
	Estimate Lower		Upper
Investigation & Remediation Costs (IR) Transaction costs	40 18	25 14	41 20
Total cost	58	43	83
Ratio of Transaction Costs-to-IR Costs	45%		

Notes: Source is Lloyd S. Dixon, Deborah S. Drezner, James K. Hammitt (RAND), 1991, Private-Sector Cleanup Expenditures and Transaction Costs at 18 Superfund Sites, Table 5.1. This study was "Supported by the U.S. Environmental Protection Agency". "Investigation & Remediation Costs" include Remedial Investigation / Feasibility Study (RI / FS), Remedial Design / Remedial Action (RD / RA) and reimbursements to EPA (per Table 3.4). Costs stated in 1991 dollars are inflation-adjusted to 2021 dollars using the GDP Implicit Price Deflator, https://fred.stlouisfed.org/series/GDPDEF#0

PRP Transaction Costs for Investigaton and Remediation of Superfund Sites

		#Sites						
DoD Agency	Total Expen-diture through FY2020,$M	Complemented Preliminary Assessment	Started Remedial Investigation	Started Long-term Cleanup	Total	% Sites in Remedial investigation	Total expenditure per Site, $M	Estimated Preliminary Assessment Cost per Site, $M
Army	74.6	54	7	0	61	11%	1.2	1.0
Navy	272.1	13	28	0	41	68%	6.6	5.3
Air Force	737.6	111	43	0	154	28%	4.8	3.8
						Average:	4.2	3.4

Notes: Source is GAO (2021), DoD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information, GAO-21-421, Table 1 and Figure 4. Estimated preliminary assessment cost per site assumes 80% of total expenditures through FY2020 were for preliminary assessment and 20% for remedial investigation.

Appendix C. Cost Impact from Restricting PFAS Incineration and Thermal Treatment

A PFAS incineration ban would significantly raise cleanup costs at NPL sites. PRPs with access can thermally treat PFAS-contaminated soil, rendering it non-hazardous for reuse onsite or disposal at municipal solid waste (MSW) landfills. According to EPA, 8% of Superfund remedial actions use thermal treatment and another 17% use offsite or onsite incineration.[1] As the following table shows, an incineration ban could increase costs for removing 3,500 tons of PFAS-contaminated soil[2] by between $0.08 million (5%) to $0.98 million (134%) per NPL site, depending on the baseline technology.

Incremental Cost for Removing 3,500 Tons of PFAS-Contaminated Soil at NPL Sites

State	Technology	Cost of Alternative		Incremental Cost ($M / Site)
		$ / ton	$M / Site	
Ban	RCRA (Subtitle C) landfill disposal	489	1.71	NA
Baseline	Thermal desorption, onsite reuse	208	0.73	0.98
	Thermal desorption, MSW (Subtitle D) landfill disposal	467	1.63	0.08

Notes: Both States of the World assume 3,500 tons contaminated soil and hauling costs (where applicable) using a 15-ton dump truck including loading/unloading, demurrage, manifest, and minimum trip charge (233 trips) amounting to $134 / ton. Ban: Adds $356 / ton ($277 / ton disposal fee plus $78 / ton hauling charge at the 380-mile average distance from an NPL site to the nearest Subtitle C landfill) for a total of $489 / ton. Baseline: Thermal desorption is $208 / ton. Onsite reuse assumes treated soil and water is clean for spreading or replacement at the site. Offsite disposal adds $334 / ton ($208 / ton for thermal desorption, plus a $56 / ton tipping fee, plus a $69 / ton hauling charge at the assumed 25-mile average one-way distance from an NPL site to the nearest MSW (Subtitle D) landfill) for a total of $467 / ton. Cost elements may not sum to the total cost per ton due to rounding. The primary source is DPRA, Inc. (2000).

A ban may impose higher costs on certain PRPs with boilers or industrial furnaces. The marginal cost of destroying soil onsite using incineration ($510 per ton) exceeds hazardous waste landfill disposal fees ($277 per ton). However, transporting bulk solids is expensive, and the 25 RCRA hazardous waste landfills are remote compared with many potential PFAS NPL sites. The Chamber's analysis finds that NPL sites located further than 499 miles (one-way) from a hazardous waste landfill would find onsite incineration more cost-effective. This affects 316 (24%) of the 1,322 sites currently on the NPL,[3] with most of the affected NPL sites located in the west.[4]

Endnotes

1. The EPA Office of Solid Waste and Emergency Response. Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition. September 2004. USEPA 542-R-04-015.
2. That is the volume that NAS-Joint Reserve Base Willow Grove in Horsham, NJ attempted to dispose of at a nearby county landfill. "Navy Official: 'Probably' no more removal of PFAS-contaminated soil". The Intelligencer. June 6, 2019
3. The analysis uses the same basic costing assumptions in the table. "Incremental Cost for Removing 3,500 Tons of PFAS-Contaminated Soil at NPL Sites". The 1,322 NPL sites are listed as reported by the EPA at "Superfund Data and Reports", https://www.epa.gov/superfund/superfund-data-and-reports. The 25 RCRA Subtitle C landfills are taken from the EPA's Toxic Release Inventory reports on waste received at RCRA Subtitle C landfills.
4. California, Oregon, and Washington account for 50% of affected NPL sites and 12% of all NPL sites

Appendix D. Acronyms and Abbreviations

AFFF	Aqueous Film Forming Foam
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COC	Contaminants of Concern
DoD	Department of Defense
EPA	Environmental Protection Agency
GAO	Government Accountability Office
HRS	Hazardous Ranking System
IR	Investigation and Remediation
LTRA	Long-term Remedial Action
MCL	Maximum Contaminant Level
MSW	Municipal Solid Waste
NDAA	National Defense Authorization Act
NPL	National Priority List
OUs	Operable Units
O&M	Operations and Management
PA/SI	Preliminary Assessment and Site Inspection
PERT	Program Evaluation Review Technique
PFAS	Per- and polyfluoroalkyl Substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane Sulfonic Acid
PRP	Potentially Responsible Parties
RD/RA	Remedial Design and Remedial Action
RI/FS	Remedial Investigation and Feasibility Study
ROD	Record of Decision
SDWA	Safe Drinking Water Act
TSD	Treatment, Storage, or Disposal

U.S. Chamber of Commerce

AGC
THE CONSTRUCTION ASSOCIATION

VIA ELECTRONIC DELIVERY

November 7, 2022

Michelle Schultz
U.S. Environmental Protection Agency
EPA Docket Center
OLEM Docket, Mail Code 28221T
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; Proposed Rule; 87 *Fed. Reg.* 54,415 (Sept. 6, 2022)

Dear Ms. Schultz:

On behalf of the Associated General Contractors of America (AGC), we respectfully submit the following comments in response to the U.S. Environmental Protection Agency's (EPA) proposal to designate PFOA and PFOS as hazardous under Section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[1] This *first-of-its-kind* regulatory action would trigger new reporting requirements and impose cleanup liability under Superfund, including increased scrutiny on current and closed Superfund sites and a potential new focus under environmental justice programs (referred to as the "proposal" or "proposed regulations").[2]

I. INTRODUCTION

AGC is the leading association for the construction industry. AGC represents more than 27,000 firms, including over 6,500 of America's leading general contractors, and over 9,000 specialty-contracting firms. More than 10,500 service providers and suppliers are also associated with AGC, all through a nationwide network of chapters. AGC contractors are engaged in the construction of the nation's commercial buildings and industrial facilities, highway and public transportation infrastructure, water and wastewater systems, flood control and navigation structures, defense installations, multi-family housing, and more. The construction industry has played a powerful role in sustaining economic growth in the United States, in addition to producing structures that enhance productivity and quality of life.

[1] *See* 87 *Fed. Reg.* 54,415 (Sept. 6, 2022) online at https://www.govinfo.gov/content/pkg/FR-2022-09-06/pdf/2022-18657.pdf.
[2] AGC of America is a member of the U.S. Chamber of Commerce. AGC encourages the Agency to review and consider the extensive comments that the Chamber is submitting to this docket.

Over the last few years, Congress and EPA have been looking at emerging concerns with ubiquitous chemicals that are found in everyday commercial products, such as per- and polyfluoroalkyl substances (PFAS). There are approximately 5,000 PFAS in use in a wide variety of common commercial products like healthcare, cosmetics, apparel, carpeting and fire retardants. PFOA and PFOS are two of the most prevalent PFAS. EPA is proposing to take a novel, first-ever approach to designate via regulation PFOA and PFOS (and their salts and structural isomers) as hazardous substances under Superfund laws. EPA has not made the case that CERCLA is the best approach, yet EPA has already announced plans to replicate this approach with more PFAS in the near future.[3]

AGC supports a measured approach to environmental challenges such as PFOA and PFOS—or other emerging chemicals of concern. AGC members will be at the front lines of any remediation efforts. Given the decades of historic uses of PFAS, as well as current uses, AGC has shared concerns with Congress and EPA that how they approach the PFAS challenge could drastically increase construction costs, increase risk, and quickly overwhelm cleanup efforts. PFAS is commonly referred to as ubiquitous; and as such, its regulation under CERCLA raises equally ubiquitous liability concerns for public and private entities. There is no approved cleanup plan for PFAS. Furthermore, EPA has not assessed the capacity of existing hazardous material landfill space and other infrastructure to manage an influx of these wastes. **AGC urges EPA to withdraw its proposal, evaluate exposure risks, prioritize efforts, and lay the foundation for necessary clean-ups through other existing authorities that allow a more nuanced and workable approach.**

II. IMPACT ON CONSTRUCTION AND DEVELOPMENT

During construction, contractors routinely engage in earthmoving, dewatering, dredging and fill activities on all types of properties. PFAS from commercial applications or thousands of commonly-used products could be present in soil or groundwater in trace or even undetectable amounts unbeknownst to the contractor working on a given project. PFOA and PFOS (and other PFAS) have been in use for several decades. Historically, it is unlikely that PFOA and PFOS (or any PFAS) would have been included in the environmental site assessments commonly used by industry (i.e., parties conducting due diligence) to identify on-site and off-site sources of potential site contamination—meaning a contractor could be blind to their liability threats.[4]

AGC does not understand why EPA does not include contractors/construction among the list of industry sectors that may be impacted by this economically significant proposal. .[5] Several of the

---

[3] *See* EPA presentation "Notice of Proposed Rulemaking: Designating PFOA and PFOS as CERCLA Hazardous Substances," August 2022: https://www.epa.gov/system/files/documents/2022-09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf.

[4] In 2021, American Society for Testing and Materials (ASTM) revised its ASTM E1527-21 for Phase I Environmental Site Assessments for the potential to address emerging contaminants (such as PFAS). Ross, J., "EPA and ASTM Incorporate PFAS Due Diligence into Environmental Site Assessments," April 26, 2022 (available online at https://www.martenlaw.com/news-and-insights/epa-and-astm-incorporate-pfas-due-diligence-into-environmental-site-assessments).

[5] *See* 87 *Fed. Reg.* at 54,416-54,417.

industries identified (among those impacted) are representative of potential future construction sites (airports, industrial mills, manufacturing facilities, and plants—as well as agricultural land) for demolition and redevelopment or for large-scale renovation or expansion projects. Furthermore, some of these industries manufacture PFAS-containing commercial products that are used in construction, such as carpet, coatings, paints, varnishes, and textiles.

The designation of PFOA and PFOS as hazardous under CERCLA would have widespread implications for the construction industry, as summarized in the examples below – all of which were mentioned in the preamble to the proposed rule,[6] mentioned by AGC members, or identified from a brief Internet search on PFAS.[7]

- Dewatering - This could include groundwater from within the project's site boundaries or the drawing in of PFAS from neighboring sites that can occur during dewatering activities.
- Earthmoving – Moving, disposal and/or reuse of previously considered "clean" fill and other materials.
- Construction and/or Demolition
    - Airports – Federal bases and airports may contain PFAS from fire-fighting foams.[8]
    - Buildings – PFAS could be found in common building materials (e.g., carpeting) or in products used during the building's operation (e.g., health care).
    - Utilities – PFAS could be found in wastewater treatment plants (or old septic systems in prior residential areas). PFAS is used in both solar and wind generation products.
    - Highway – Vehicles contain products with PFAS, therefore, work on highway and transportation projects could come across trace amounts from vehicles or accidents (PFAS can be used as a vapor suppressant for hydrocarbon fuels).
    - Greenspaces – A recent study[9] in three states demonstrates that even pristine areas have background levels of PFAS (primarily PFOS and PFOA).

---

[6] *See* 87 *Fed. Reg.* at 54,417.

[7] AGC found these examples through an informal and incomplete literature search. AGC provides this information solely to highlight potential ways in which a construction contractor may encounter PFAS on everyday project sites. AGC did not complete a formal literature review study on PFAS and does not weigh in on whether the studies mentioned are scientifically valid. Examples: Our Current Understanding of the Human Health and Environmental Risks of PFAS | US EPA; An overview of the uses of per- and polyfluoroalkyl substances (PFAS) - Environmental Science: Processes & Impacts (RSC Publishing) DOI:10.1039/D0EM00291G; Septic systems as sources of organic wastewater compounds in domestic drinking water wells in a shallow sand and gravel aquifer - ScienceDirect; Environmental Factor - March 2019: PFAS — a problem in North Carolina drinking water (nih.gov); Per- and Polyfluoroalkyl Substances (PFASs) detected in Source Waters and Treated Public Water Supplies | U.S. Geological Survey (usgs.gov); Concerns grow over PFAS-tainted sewage sludge spread on croplands | Great Lakes Now; PFAS in landfills and wastewater - EHN; PFAS in Sewage Sludge, Industrial Wastewater Targeted for Rules (bloomberglaw.com); Waxing activity as a potential source of exposure to per- and polyfluoroalkyl substances (PFAS) and other environmental contaminants among the US ski and snowboard community - ScienceDirect

[8] DOD has identified more than 400 active and former military installations with known or suspected PFOA or PFOS contamination, most likely attributable to the use of firefighting foam, and has been working via a task force since 2019 to address potential contamination. DOD Moving Forward With Task Force to Address PFAS > U.S. Department of Defense > Defense Department News

- Other - Projects on soil that was irrigated with potable water (e.g., a lawn) or fertilized with wastewater sludges (e.g., cropland) could also contain a certain level of PFAS. Projects near ski lodges may find PFAS from the use of ski waxes, which can abrade onto snow. Dust from neighboring properties could transport via aerial deposition PFAS to sites without known prior use.

AGC urges EPA to more fully vet the financial impact that the proposed designation will have on construction (and other) companies. As seen from the examples above, the implications and costs to construction will be widespread. AGC is concerned that without a risk-based approach, any necessary remediation efforts will be overwhelmed and critical infrastructure and clean energy projects[10] will be mired in liability and mitigation. AGC maintains that EPA is acting too quickly, acting arbitrarily and capriciously, and not properly complying with the Regulatory Impact Analysis and Regulatory Flexibility Act requirements

What is more, and as further supported by the discussion below, AGC questions whether CERCLA is the right tool for this designation. This will be the first time EPA has used CERCLA instead of one or more of its other, commonly used regulatory tools to make a hazardous designation. CERCLA is unwieldy and triggers extreme liability for remediation. PFOA and PFOS are considered ubiquitous, meaning that trace amounts are found nearly everywhere. Yet there are limited treatment options and only one disposal option: in a hazardous waste landfill. EPA has set 70 ppt as the preliminary remediation goal for PFOA and PFOS contamination in groundwater, none for soil, and published near-zero draft advisory levels for drinking water.[11] It is not at all clear what standards may apply in a PFOA or PFAS cleanup action. And there is a lack of research on exposure routes and evaluation of risks to the public based on those exposures. EPA cannot even determine the extent of potentially contaminated sites.[12] CERCLA's reporting mechanism will not shed light on potentially contaminated sites—as the legacy of its historic use is greater than its current limited usage. CERCLA will prevent the agency from limiting liability for non-responsible parties.

A. Statutory, Regulatory and Contractual Liability – and Third-Party Claims

Innocent contractors need protection against statutory/regulatory legal liability for contamination associated with the active sites on which they currently work as well as completed projects. In public meetings, EPA has indicated that it will allow for "enforcement discretion,"[13] but that discretion is

---

[9] Massachusetts Soils Study Sheds Light on Background PFAS Concentrations - Woodard & Curran (woodardcurran.com)
[10] PFAS is also integral in renewable energy (solar, wind, battery) technologies that will help the Biden Administration meet its carbon reduction goals. Understanding these complex issues and prioritizing any mitigation actions will be essential to move forward in a balanced and sustainable approach.
[11] EPA acknowledges that the interim levels are below levels at which existing analytical methods can even measure PFAS in drinking water, but the agency has not indicated the number will be revised once this proposal is finalized.
[12] *See* 87 *Fed. Reg.* at 54,423
[13] *See* EPA presentation "Notice of Proposed Rulemaking: Designating PFOA and PFOS as CERCLA Hazardous Substances," August 2022: https://www.epa.gov/system/files/documents/2022-

not enough of an assurance. Should hazardous substances be discovered on a site, any contractor connected with that site could be drawn into a legal battle over who is financially responsible for cleaning up the site affected by PFOA/PFAS contamination.

Under CERCLA's strict, retroactive, joint and several liability, EPA requires Potentially Responsible Parties to clean up sites contaminated by hazardous substances regardless of fault. CERCLA makes no distinction when assigning responsibility to the source of a substance designated as hazardous -- or to the quantity of the substance introduced by the party. A hazardous substance designation for PFOA/PFOS also would force the reopening of Superfund, including Brownfield sites, that have already undergone redevelopment. Given the extremely small amounts EPA is considering (presumably less than the 70 ppt guidance for remediation of groundwater), these sites may be in a permanent state of rehabilitation—meaning the risk will be ongoing.

AGC has long shared its members' concerns about the multiple routes by which an innocent contractor may be ensnared in Superfund liability. Generally, the following groups, called Potentially Responsible Parties or PRPs, may be responsible to pay for or perform Superfund cleanups: 1) current owners or operators of a contaminated facility; 2) past owners or operators of a contaminated facility at the time hazardous substances were disposed of; 3) generators of hazardous substances found at the site; and 4) transporters that sent waste to the contaminated facility. Depending on the circumstances, general contractors could fall in any of these four categories.

Courts have uniformly held that CERCLA imposes strict liability, regardless of fault. Should hazardous waste be discovered on a site, any contractor performing work on that site could be drawn into a legal battle over who is financially responsible for cleanup of the hazardous waste at the site. The case, *Kaiser Aluminum & Chemical Corp. vs. Catelus Dev. Corp.*, 979 F.2d 1338 (9th Cir. 1992) demonstrates how an innocent contractor performing nonremediation work can be held liable for cleanup of the hazardous waste on a site, even though the contractor had no responsibility for the hazardous waste and did not own the property. The construction contractor was hired to grade and prepare the site for a housing development. This required excavation and dispersal of soil on site. No soil was removed from the site and no soil was brought onto the site. After the contractor's work was underway, it was discovered that hazardous chemicals deposited in the 1940's contaminated the site. Once the contamination was discovered, the owner sued the developer who, in turn, sued the contractor. In the 9th Circuit Court of Appeals, the contractor was found liable for cleanup costs as an operator of a hazardous waste site.[14]

Contractors may face an increased risk of CERCLA liability due to the language in the construction contract that outlines their scope of work and the contractor's role and responsibilities on the jobsite. *See* Appendix I below. A hazardous substance designation for PFOA/PFOS would impact contractual obligations between general contractors and their owner/developer clients and

---

09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf.

[14] See also, *BancorpSouth Bank v. Envtl. Operations, Inc.*, 908 F.Supp.2d 1016 (E.C. Mo. 2012 finding contractors on site spread hazardous substances creating a basis for operator liability).

suppliers/service providers, as well as legal claims/litigation. For example, if a contractor used fill material from a quarry and did due diligence at the time to determine the fill was "clean," yet later tests show PFOA or PFOS contamination, then the property owner will seek legal action against the contractor—who would then need to seek compensation from the quarry. Furthermore, contract specifications that tell the contractor to select disposal sites or to identify an outside source of a material will pose a huge risk to the contractor for liability. Members are also seeing requirements for contractors to conduct extensive environmental tests on all material added to the site (e.g., aggregates, soil, etc.). Whereas this will help identify some contamination, it will not help with undetectable amounts. And it will drive up costs for projects. Contractors will not only need to be concerned with activities related to project sites, but with their own yards and laydown areas. Lastly, unaware contractors may inadvertently sign off as generators or transporters.

AGC strongly urges EPA to focus on exposure risks to inform priority actions and educate the public. The massive scale of potential contamination by extremely small almost undetectable amounts of PFAS is already making its way into public discourse, signaling a wave of litigation to come and public panic and possible misinformation.[15] Environmental groups are releasing reports presuming contamination of incredibly large numbers of properties and waterways.[16] The media is sharing reports about amounts as low as 1 ppt.[17] As mentioned above, PFAS has been found in 88 out of 100 samples taken in pristine areas in a three-state study (84 percent contained PFOS).[18] An AGC member company that specializes in remediation work has shared that homeowners are already taking samples of the dirt in their backyards to have it analyzed. (EPA does mention that eating dirt could be a possible route of exposure[19] but should provide some clarity to the public about what risks their backyards actually pose.)

B. Limited Clean Up, Disposal and Destruction Options

AGC members have shared that there are limited options for the treatment or disposal of PFAS. For treatment of water, one can filter/treat the water and then dispose in hazardous waste sites the treatment media (granular activated carbon, filters, and bags), sludge, sediments, and other solids. Ion exchange resin is another option, but the resins must be discarded and replaced after use, which is also expensive. There are no viable treatment options for soil except for disposal in a landfill. Advanced treatments are in the development phase. However, field trials and rollout could be years away and the costs of those treatments are unknown.

Disposal in a hazardous waste landfill will be the preferred method until EPA approves other treatment, disposal, or destruction methods. However, space in hazardous waste landfills is limited and carefully managed as they are difficult to permit. Disposal capacity can be quickly overwhelmed

[15] Lawyers Warn EPA's CERCLA Listing Will Expand PFAS Litigation | InsideEPA.com
[16] PFAS pollute 83% of U.S. waterways - E&E News (eenews.net); Scientists say PFAS contamination should be presumed at over 57,000 US (scienmag.com)
[17] Testing reveals PFAS chemicals in West Branch of Susquehanna River | State | wfmz.com
[18] Massachusetts Soils Study Sheds Light on Background PFAS Concentrations - Woodard & Curran (woodardcurran.com)
[19] Our Current Understanding of the Human Health and Environmental Risks of PFAS | US EPA

with contaminated soil and treatment media. It is not clear whether the treatment media can be recharged and reused safely, so it also will likely be disposed of in hazardous waste landfills. EPA needs to revisit its capacity assessment[20] prior to the hazardous waste designation taking effect to ensure there are safe and acceptable means to manage the large quantities of soil and other wastes anticipated to be generated.

EPA will need to factor not only PFOA and PFOS waste into their waste calculations, but PFAS in general due to the growing stigma and fear of liability. Lacking guidance from EPA on appropriate thresholds, members are finding landfills to be risk-averse to taking any PFAS into nonhazardous facilities because of Superfund liability. Even after EPA develops the threshold for remediation, members caution that landfills will not take anything close to what the federal threshold would be due to liability. Furthermore, reports are already coming out that remediated Superfund sites could need to be reopened to address PFOA or PFOS.[21]

EPA has not established official cleanup levels or thresholds; such standards will significantly affect the cost and impact of the proposed action. The lower the threshold the more costly compliance will be as more sites will be pulled into the Superfund program—as well as more waste and used treatment media will be generated and need to be disposed of in a hazardous waste landfill. (EPA's health advisory for drinking water is below detectable levels.)

III. REGULATORY IMPACT ANALYSIS

The White House Office of Management and Budget determined the proposal is economically significant and ordered the Agency to conduct a regulatory cost-benefit analysis. AGC finds that EPA's analysis is lacking and incomplete. For example, EPA ignores the remediation costs that would result directly from the proposed action. There are also operational costs that would arise, such as training and certifications and additional layers of complexity added to project coordination; none of which are accounted for in the Agency's analysis. For example, the U.S. Chamber of Commerce's assessment is over 17.4 billion dollars for existing non-federal national priority sites alone.[22] EPA must conduct a comprehensive regulatory impact analysis that factors in treatment/disposal and training and business operations costs as outlined below.

Treatment itself comes with a cost. A member shared a dewatering example, treating 10,000 gallons of water could use two units of granular activated carbon and four filter bags, adding some cost. At a million gallons, you could use over 100 filter bags. Treatment costs could easily amount to 0.50 cents

---

[20] Pursuant to CERCLA, EPA must assess hazardous waste capacity to meet ensure future needs. Assessment of National Capacity for Hazardous Waste Management | US EPA; When last reviewed in 2019, "EPA does not believe that any current hazardous waste regulatory activities will substantially alter management behaviors within the next five years." (Assessment Report, 2019, pg. 8.) Certainly, the current proposal will change those projections. In the 2019 report, EPA includes a list of commercial hazardous waste landfills that numbers only 18 facilities (one of which is filled to capacity and capped). (See pg. 19.)

[21] See for example: What-could-the-us-epas-proposed-superfund-listing-for-pfoa-and-p.pdf (huntonak.com); PFAS and Waste Industry CERCLA Concerns - CMBG3 Law.

[22] https://www.uschamber.com/environment/pfos-and-pfoa-private-cleanup-costs-at-non-federal-superfund-sites

or more per gallon, leading to $500,000 in hazardous waste costs in this particular example. The testing and permitting for dewatering effluent can also be costly and time-consuming; even when dewatering on projects at the wastewater treatment facility itself. Treatment will also result in waste materials that will need to be hauled, sometimes long distances, to the limited available commercial hazardous waste landfills. This is especially true with contaminated soil that will be expensive to transport in mass quantities.

In addition to the cost of treatment, EPA also needs to consider the costs of trained personnel. Anyone engaged in the site that can come into contact with hazardous waste, even if turning the site over to a specialized contractor to remediate, would need to receive HAZWOPER training. Individuals involved with a contaminated site will need to take part in the 40-hour training, including medical monitoring and refreshers. Some may also need an 8-hour supervisor training. It would cost approximately $1,000 per person for the 40-hour training, which can be conducted online, but the contractor would have to pay that week's salary in wages. Respirator fitting is only done in person and would cost an additional $500 per person. Medical monitoring includes establishing a baseline and conducting annual exams. Given the ubiquitous nature of PFOA and PFOS (or any PFAS), it will be hard to ascertain whether any spikes are due to conditions on the site or from handling a fast-food wrapper, using shampoo, or wearing body lotion or scents. For example, PFAS testing is so sensitive that professionals have a three-day process beforehand to prepare to take samples. They even must use special soaps and clothing detergents prior to sampling to avoid false readings.

Designation would also directly impact scheduling and coordination—adding layers of complexity and cost on construction sites. Site conditions and any necessary demolition will need to be thoroughly tested and any remediation addressed prior to new construction. Products used on the site previously would need to be researched. For example, before the demolition of a commercial building a contractor may need to separate carpet and coatings in pipes, etc., and there will be additional abatement costs. (Note that as there are no rules to guide the disposal process, demolition contractors will have no direction for handling or disposing of any potentially contaminated materials. Likewise, landfills that previously accepted materials may not accept new wastes until they could be certain the waste would not add to their own liability. Demolition construction could come to a halt without specific direction.) As mentioned above, any added materials will need to be extensively tested—which is not a guarantee that better testing methods in the future will not find some trace.

IV. REGULATORY FLEXIBILITY ACT

AGC is concerned that EPA has failed to engage in the necessary and required outreach to the small business community to ascertain more fully the impacts of the proposed action. The Agency fails to recognize the impact this proposal will have on mitigation and liability, and in doing so has not engaged in a thorough small business review nor does their economic analysis reflect the breadth of impacts. The Agency improperly certified that the proposal does not need to go through the Regulatory Flexibility Act (RFA) Small Business Regulatory Enforcement Fairness Act (SBREFA) process. Given the OMB finding that the proposal is significant, EPA should conduct an Initial Regulatory Flexibility Analysis, convene a SBREFA panel, and complete a thorough economic analysis.

V. CONCLUSION

AGC urges EPA to withdraw the proposal. EPA has not sufficiently considered the widespread implications of its proposed course of action—ignoring impacts to innocent contractors and creating significant liability for public and private entities. EPA is proposing this action in the absence of sufficient treatment, disposal, or destruction options. EPA has not justified why it seeks to designate a CERCLA hazardous substance by rulemaking (for the first time) instead of using one of its other regulatory authorities and avenues to address PFOA and PFOS (and additional PFAS in the future). The agency could have proposed action under CERCLA as a "pollutant or contaminant" or through the Resource Conservation and Recovery Act or the Safe Drinking Water Act, thereby avoiding the inescapable and inequitable liability scheme under CERCLA's hazardous designation. EPA should focus on prioritizing efforts based on exposure risks. EPA also needs to conduct a comprehensive regulatory impact analysis. Furthermore, EPA has failed to engage with small businesses about potential impacts.

If you have any questions, please reach out directly to Melinda Tomaino at melinda.tomaino@agc.org or (703) 837-5415.

Sincerely,

Melinda Tomaino

Melinda L. Tomaino
Director, Environment and Sustainability

Leah Pilconis

Leah Pilconis
Vice President and Counsel, Risk Management

APPENDIX I

As construction projects get larger, owners are pushing responsibility to the general contractors to manage, hire consultants, remediation specialists, and resolve site conditions. With increased frequency (and particularly on critical infrastructure projects), contractors are expected to manage environmental risk, including:

- Perform all HazMat encountered – government approvals, environmental protection plan
- Hire HazMat consultant
- Obtain bids, hire subcontractors to deal with HazMat and dispose off-site
- Owner pays costs and increases time for HazMat

Example 1:

Dealing with environmental conditions transferred to the contractor—

> "7.1.1.1 Except as otherwise provided in this Section 7.7.1, Design-Builder shall, as part of the D&C Work, perform, or cause to be performed, all Hazardous Materials Management required in connection with the Project in accordance with applicable Law, Governmental Approvals, the approved Environmental Protection Program, and all applicable provisions of the DBC Documents."

Contractor hires consultants—

> "7.1.1.3 Design-Builder shall obtain Developer's approval of one or more independent hazardous material consultants (the "Hazmat Consultant") that will perform assessments of any Hazardous Materials encountered in connection with the Project, the Site or the D&C Work."

Dealing with environmental conditions transferred to contractor –

> "7.1.1.1 Except as otherwise provided in this Section 7.7.1, Design-Builder shall, as part of the D&C Work, perform, or cause to be performed, all Hazardous Materials Management required in connection with the Project in accordance with applicable Law, Governmental Approvals, the approved Environmental Protection Program, and all applicable provisions of the DBC Documents."

Example 2:

Contractor hires the subcontractors—

> "The Contractor's geotechnical engineer shall review all available geotechnical information provided in the Contract package and become familiar with the soil and site conditions at the project site by visiting the site. During the site visit and in subsequent phases of the project, the Contractor shall examine and/or verify the

> information provided and obtain any additional information to complete the design and construction of the project. **The Contractor remains solely responsible and liable for design sufficiency and should not depend on reports provided by the [Government] as part of the contract documents.**"

Example 3:

Reimbursement for Costs—

> "12.2.4 Costs and Delays. Except for Owner Release(s) of Hazardous Materials, except as set forth in Sections 12.2.3 and 12.3 and without limiting Owner's role or responsibilities set forth in Section 12.2.5, **Contractor shall not be entitled to any compensation due to increased costs or delays associated with the discovery, handling, storage, removal, remediation, transport, treatment or disposal of Hazardous Materials**, including contaminated groundwater, encountered in construction of the Project or Utility Adjustments."

American Chemistry Council

November 7, 2022

The Honorable Michael S. Regan
Administrator
US Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Designation of perfluorooctanoic acid (PFOA)and perfluorooctanesulfonic acid (PFOS) as CERCLA hazardous substances, Proposed Rule, 87 *Federal Register* 54415 (September 6, 2022), EPA-HQ-OLEM-2019-0341

Dear Administrator Regan:

The American Chemistry Council (ACC) submits the enclosed comments on the proposal to designate perfluorooctanoic acid (PFOA)and perfluorooctanesulfonic acid (PFOS) as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). ACC supports efforts to accelerate remediation of PFOA and PFOS contamination to protect public health and the environment that are supported by the best available science. The proposal to designate these substances under CERCLA will not result in a faster pace of cleanups. Instead, designation will slow remediation efforts as responsible parties struggle with CERCLA's strict liability system. As discussed in the enclosed comments, EPA already has sufficient enforcement tools at its disposal to address PFOA and PFOS without the designation them as hazardous substances.

Given the potential for significant impacts across both the public and private sectors, the Agency should withdraw the current proposal and explore greater use of its existing tools.

Sincerely,

Steve Risotto

Stephen P. Risotto
Senior Director

Enclosure

direct cost") together with, to the extent feasible, a quantification of those costs. Circular A-4 recommends monetizing quantitative estimates whenever possible.

The Agency's economic analysis identifies and quantifies, in cursory fashion, the direct impact of the proposed rule:

- reporting of releases equal to or greater than the reportable quantity to the National Response Center;
- disclosure of the storage or release of a hazardous substance during the sale or transfer of federal property; and
- listing by the Department of Transportation of the hazardous substance in the Hazardous Materials Regulations under the Hazardous Materials Transportation Act.

However, this description fails to capture all of the expected additional costs of the proposed rule. Table 1 below illustrates three categories of social costs. The first of these—costs associated with reporting of future releases—are acknowledged in the Agency's economic assessment. To the extent the proposal yields little to no new information on releases (given that these chemicals have been phased out of production and use in the US), it lacks practical utility — raising a significant question about the merit of the information collection request accompanying the proposal.[5]

The second category of cost relates to waste management practices. The Agency devotes scant attention to this behavioral response, simply suggesting that waste management activities will adjust to encourage prevention of potential releases. Although some adjustment can be beneficial, too much can be detrimental—an issue left unaddressed in the economic assessment. An *over-adjustment problem* occurs when social costs exceed social benefits. For example, a slower pace for cleanup under the Brownfields Program[6] will reduce the number of brownfields transactions, which have a very favorable benefit-cost ratio.[7] More municipalities will be required to treat landfill leachate before sending it to a publicly owned treatment work (POTW), raising costs.[8] POTWs will reduce the amount of biosolids sold for agricultural

---

5 The Paperwork Reduction Act (PRA) requires that agency information collections must "maximize practical utility and public benefit" and "minimize burden." The proposed rule represents an information collection and therefore is subject to the standards of the PRA.

6 42 U.S.C. Section 9601(39).

7 Haninger K *et al*. The value of brownfield remediation. *J Assoc Environ Resource Economists*, *4*(1):197-241 (2017). https://www.journals.uchicago.edu/doi/full/10.1086/689743

8 Letter to Ariana Sutton-Grier, Office of Management and Budget from Darrell K. Smith, National Waste and Recycling Association. PFAS Management Costs for Municipal Solid Waste Landfills (February 8, 2022).

application and will be forced to find other options for handling this material, reducing revenues and increasing costs. Industrial waste managers will divert higher-PFAS-concentrated waste from Class D municipal landfills to more expensive Class C landfills. The expected costs are likely to increase significantly as responsible parties scramble to identify the limited options available to meet CERCLA requirements. Competition and price increases due to a dwindling capacity available in the Class C landfills will drive out low bids, putting PFAS disposal at a premium, which will result in passing cost down to consumers and the US economy as a whole. And, as waste management practices change, so might the availability of products made from perfluorinated substances as some manufacturers seek to limit potential liability, which will reduce consumer demand and producer supply. We believe over-adjustment can be expected due to CERCLA's unique liability provisions.

Table 1. Social Costs of the Proposed CERCLA Rule.

Impact	*Concern/Problem*	*Applicability*	
		PFOA/PFOS	*Other PFAS*
reporting of releases	releases above RQ unlikely	✓	NA
changes in waste management	over-adjustment due to CERCLA liability concerns	✓	✓
additions to the NPL	CERCLA utilized over other, more cost-effective authorities	✓	✓

The third category of cost relates to CERCLA's remediation program. The proposed designations would allow EPA and other agencies to require cleanups and recover response costs and allow private parties to file claims for cost recovery and contribution. The designations could result in some sites being added to the NPL,[9] significant increases in sampling, analysis, and delineation at existing sites, amendments to sites implementing EPA

https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=2050-AH09&meetingId=114123&acronym=2050-EPA/OLEM

9 In the past, EPA has adopted Safe Drinking Water Act Lifetime Health Advisories (LHAs) as interim cleanup levels via guidance. States have adopted LHAs as groundwater cleanup levels for state superfund program sites. With the new interim LHAs for PFOA/PFOS (where the cleanup level is now close to zero), sites with trace levels of PFOA or PFOS could be eligible for NPL listing. This could greatly expand the number of potentially responsible parties, citizen suits, and private party actions.

selected remedies, triggering the reopening of previously closed CERCLA sites, and the initiation of costly private party litigation unbounded by any Agency discretion or any reasonable evaluation of risk. PFOA and PFOS could be included in the scope of all Phase I Environmental Site Assessments in order to satisfy numerous "hazardous substance" aspects of the "all appropriate inquiries" rule. EPA has completely failed to identify and evaluate these potential costs – which are expected to be substantial. Although some additional use of CERCLA can be beneficial, too much can be detrimental. An *over-use problem* arises when sites are addressed by mandating a remedy for PFOA and PFOS under CERCLA versus other, more cost-effective remediation programs (see discussion below).[10] We believe overuse can be expected because the size of the CERCLA Superfund budget (which is expected to increase significantly due to recent legislation) will provide funds for regulators tasked with overseeing remediation of hazardous waste sites.

Importantly, two of these categories of indirect costs are not limited to PFOA and PFOS. EPA's actions could be seen as a precedent for future designations of additional PFAS – a group of thousands of chemicals with vastly different properties and risk profiles.

We recommend that the Agency revise its economic assessment to not just identify issues, but to quantify all of the impacts of the proposed rule, both direct and indirect. Quantification and monetization are needed to meet the standards set by EO 12866 and Circular A-4. The Agency cannot dismiss such an exercise simply because precise information is unavailable. Rather, the Agency' failure to capture the uncertainties and to appropriately weigh them as a reason to withdraw the proposed CERCLA listing. In fact, the lack of available information strongly suggests that the Agency should not move forward with this action until more data are gathered.

EPA does not consider a reasonable number of regulatory alternatives

Circular A-4 recommends that agencies consider a manageable number of alternatives including those that differ in terms of stringency. For each, benefits and costs should be assessed. EO 12866 is based on the principle that regulation should maximize net benefits within the statutory discretion of the agency. As discussed below, EPA has several enforcement tools available to it. The Agency has not identified these tools or any other approaches as regulatory alternatives in its economic assessment.

---

[10] For more information on the costs of federal Superfund sites, see Congressional Budget Office. *The Total Costs of Cleaning Up Nonfederal Superfund Sites*, Congress of the United States (1994). https://www.cbo.gov/sites/default/files/103rd-congress-1993-1994/reports/entirereport_11.pdf#:~:text=According%20to%20a%20new%20Congressional%20Budget%20Office%20%28CBO%29,more%20and%20could%20continue%20through%20the%20year%202075.

EPA has failed to characterize uncertainty

Although EPA's economic assessment points to various uncertainties in support of its decision to exclude consideration of cost in its proposal to designate PFOA and PFOS as hazardous substances, several groups have developed estimates of the likely impacts. Among those estimates is a report by the US Chamber of Commerce which suggests that the annualized cleanup costs at National Priorities List (NPL) sites over the next 30 years would total as much as $1.1 billion[11] based on the Department of Defense's (DOD) experience in remediation at military sites to the existing criteria established by EPA. The expected costs will increase substantially once EPA establishes drinking water standards for PFOA and PFOS in 2023 as the number of affected sites, and the cost per site, increase.

In considering uncertainties, OMB's Circular A-4 recommends that –

> Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. . . When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information. . . .For major rules involving annual economic effects of $1 billion or more, you should try to provide some estimate of the probability distribution of regulatory benefits and costs.

In its economic assessment, the Agency acknowledges significant uncertainties in the estimated impact of the proposed rule, including -

- the number of sites with PFOA or PFOS contamination that would require cleanup,
- the extent and type of PFOA and PFOS contamination at these sites;
- the extent and type of other contamination at the sites;

[11] US Chamber of Commerce. PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites (June 2022). Submitted to the Office of Management and Budget. https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule-false&rin2050-AH09&meetingId=113973&acronym-2050-EPA/OLEM

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2021, Congress imposed several requirements and obligations on the DoD with regard to PFOA and PFOS. For example, Section 335 required DoD to publicly disclose the results of any testing for PFOA, PFOS, and other PFAS conducted on military installations or formerly used defense sites, regardless of who conducted the testing. In addition, Section 332 required the DoD, when conducting removal or remedial actions pursuant to PFOA and/or PFOS contamination found in drinking or ground water to ensure that they achieve the most stringent of any enforceable state and federal drinking, surface, or groundwater standards or health advisories issued pursuant to the SDWA.

EPA has not established that sufficient capacity exists for the disposal and destruction of waste containing PFOA and PFOS

As a result of designating PFOA and PFOS as hazardous substances, generators of wastes containing these substances will need to find appropriate methods for their disposal. Among the concerns identified with CERCLA response actions is the availability of sufficient capacity for the disposal of the material that is generated.[55] In the case of the PFOA and PFOS, this material may include contaminated soil, spent granular activated carbon generated from treating contaminated water sources, and biosolids from wastewater treatment works. One estimate suggests that the number of sites potentially requiring remediation may total in the tens of thousands.[56]

EPA's 2020 disposal/destruction guidance does not provide sufficient clarity on practices that are acceptable to EPA

Despite the likely need for increased capacity for the disposal of wastes containing PFOA and PFOS if those substances are considered "hazardous substances" under CERCLA, EPA has not attempted to evaluate whether sufficient disposal capacity exists. In fact, EPA has not provided clear guidance on what disposal options it considers to be appropriate for PFOA and PFOS. Draft interim guidance released by Office of Land and Emergency Management (OLEM) in 2020 discusses three possible disposal/destruction approaches that may be effective and are commercially available – landfilling, thermal treatment, and underground injection. However, the EPA report notes -

---

[55] An assurance of the availability of hazardous waste disposal capacity is a requirement of remedial response action for hazardous substances under CERCLA Section 104(c)(3).

[56] Salvatore D *et al.* Presumptive contamination: a new approach to PFAS contamination based on likely sources. *Environ Sci Technol Lett* 100(37): 2c00502 (2022). https://doi.org/10.1021/acs.estlett.2c00502

American Forest & Paper Association

November 7, 2022

Michelle Schultz
Office of Superfund Remediation
and Technology Innovation (5202T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Re: **EPA Proposed Rule: Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; Docket ID No. EPA-HQ-OLEM-2019-0341**

Dear Ms. Schultz:

The American Forest & Paper Association (AF&PA) appreciates the opportunity to provide comments and recommendations on EPA's proposed rule to list PFOA and PFOS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund).[1]

Introduction

Overview of AF&PA

AF&PA serves to advance U.S. paper and wood products manufacturers through fact-based public policy and marketplace advocacy. Our members make essential products including pulp, packaging, printing papers, tissue, wood products, and a range of other products that are among the most used and necessary items for people in the U.S. and abroad – and are made from renewable and recyclable resources.

The forest products industry accounts for approximately four percent of the total U.S. manufacturing GDP, manufactures nearly $300 billion in products annually and employs approximately 950,000 people. The industry meets a payroll of approximately $60 billion annually and is among the top 10 manufacturing sector employers in 45 states.[2]

---

[1] 87 Fed. Reg. 54415 (Sept. 6, 2022).
[2] AF&PA 2030 Sustainability Goals, https://www.afandpa.org/2030

AF&PA's sustainability initiative — *Better Practices, Better Planet 2030* — comprises one of the most extensive quantifiable sets of sustainability goals for a U.S. manufacturing industry and is the latest example of our members' proactive commitment to the long-term success of our industry, our communities and our environment. We have long been responsible stewards of our planet's resources.

Our Contributions to the Circular Economy

The paper and wood products industry's role in supporting a circular economy is present along the entire value chain. Our industry contributes to a circular economy by sourcing renewable raw materials from sustainably managed forests; optimizing product design and maximizing efficient manufacturing processes to reduce waste; and improving recycling of our industry's products to keep materials in use – while providing essential products that people use every day.

Paper products are integral to the quality of life enjoyed in America. Applications include printing and writing, packaging, towel and tissue, and a variety of products that are important in our daily lives. These products are manufactured in highly efficient processes, often powered by carbon-beneficial bioenergy produced from residuals of the manufacturing process. The use of forest-derived products is one way to reduce the use of fossil fuels, and paper products can be recycled, composted, and effectively disposed of in a safe and convenient way when necessary.

Two-thirds of the paper used in the U.S., about 50 million tons each year, is recycled[3] and used to make new sustainable paper products people use every day. Recycled paper and packaging fibers can be reused five to seven times to make new products.[4] Approximately 80 percent of U.S. paper mills use some recycled paper fiber to make products like packaging, office paper, newspaper, toilet paper, napkins and paper towels.[5]

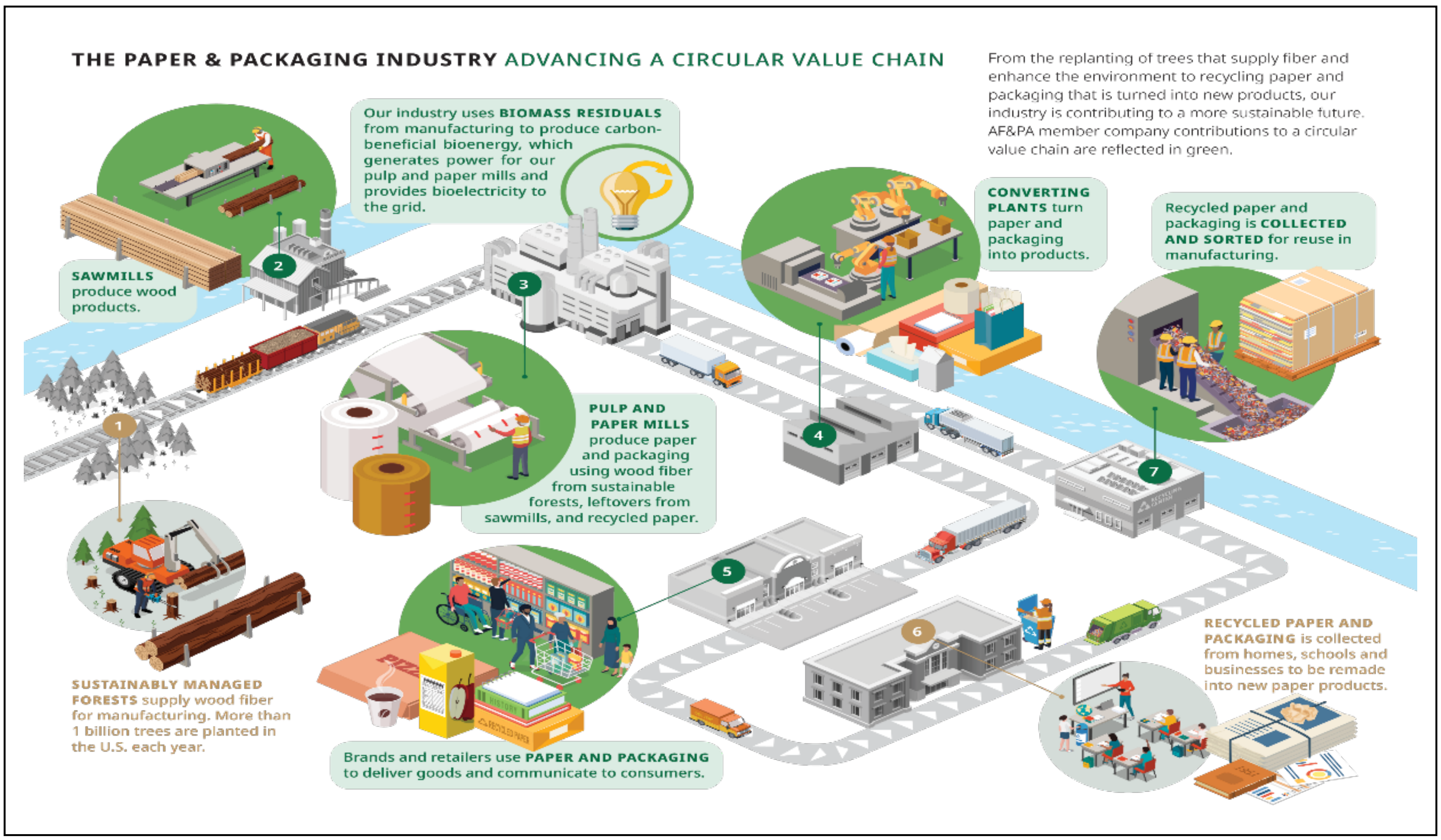
As part of AF&PA's 2030 sustainability goals, the industry aims to advance a circular value chain and continue to improve the sustainability of our products to meet evolving

[3] AF&PA Annual Statistical Summary of Recovered paper Utilization, 36th Edition, June 2022.
[4] TAPPI, How is Paper Recycled? (Paper U, Earth Answers: 2001). https://tappi.org
[5] Approximately 80 percent of U.S. paper mills use some recycled paper fiber to make products like packaging, office paper, newspaper, toilet paper, napkins and paper towels.

consumer needs. This includes innovating manufacturing processes, products and packaging, as well as increasing the utilization of recycled fiber and wood residuals in manufacturing across the industry to 50 percent by 2030.

The industry also has announced approximately $5 billion in manufacturing infrastructure investments by the end of 2023 to continue the best use of recycled paper in our products. That is nearly $2.5 million per day. Those investments will enable the industry to use an additional 8 million tons of recovered fiber in manufacturing annually.

The infographic below outlines the circular economy benefits of the pulp and paper industry:



Executive Summary

We are concerned that the listing of PFOA and PFOS as hazardous substances under CERCLA could have the unintended outcome of impeding or preventing the safe and beneficial use of paper mill residuals. As discussed more fully below, paper mills generate significant volumes of residuals, composed primarily of cellulose (wood fibers) captured from wastewater treatment. A substantial proportion of these residuals are beneficially applied on farmlands and forestlands to promote plant growth. Although per- and polyfluoroalkyl substances (PFAS) such as PFOA and PFOS are widespread in the environment, their presence in mill residuals is incidental and below indicators of ambient background levels, such as house dust. Without clarity from EPA about what levels are safe and acceptable, there could be significant stigma and perceived risk to continuing to use these residuals as a soil amendment. That not only could cause adverse economic impacts on many mills and significant job loss, but also would lead to increased landfilling of these residuals – to the detriment of the environment and many local communities. Thus, AF&PA has a very substantial interest in this rulemaking.

In our comments below, we explain:

- Paper mill residuals can continue to be safely and beneficially land applied for agronomic value, to promote plant growth, and to provide other important societal benefits.

- EPA has more than ample legal authority, under CERCLA Sec. 102(a) and the fertilizer exclusion in CERCLA Sec. 101(22)(D), to recognize this beneficial practice and to ensure it continues in a safe and sustainable manner while avoiding unintended outcomes. Indeed, Sec. 102(a) requires consideration of all relevant factors, including costs, in a hazardous substance listing decision, and certainly allows consideration of costs and unintended outcomes.

- If EPA does not exercise its legal authority to provide for the safe and beneficial land application of mill residuals, there could be many unintended outcomes, including unwarranted economic costs and job impacts, as well as adverse environmental and public health costs, which should be carefully considered.

Discussion

I. Background on Paper Mill Residuals and Recommendations to Clarify the Preamble

A. Overview of Paper Mill Residuals

In the paper making process, a large quantity of residuals is generated — around 2.5 million dry metric tons per year in the United States.[6] Paper mill residuals typically are largely composed of tree fiber (i.e., cellulose) residuals from primary, and occasionally secondary, wastewater treatment.[7] As part of the industry's sustainable use of materials, the trend to use residuals in a beneficial manner is increasing compared with landfilling. For example, from 1979 to 2016, paper mill residuals management has increased land application by 700%, while decreasing landfilling and lagooning by about 60% and increasing energy recovery by 280%.[8] Land-applied residuals are beneficial for farmlands and forestlands because they can increase soil nutrient-holding capacity, reduce soil erosion and the need for irrigation, and reduce soil compaction, which significantly improves plant growth.

B. The U.S. Paper Industry's Transition Out of PFAS

The U.S. paper industry does not make or use PFOA and PFOS in the papermaking process. Over a decade ago, the pulp and paper industry ceased using long-chain PFOA and PFOS for limited specialty applications (particularly grease- and moisture-resistant packaging) and shifted to short-chain PFAS approved by Food and Drug Administration (FDA) as safe for food packaging. PFAS that may degrade into PFOA and PFOS also have been phased out by industry and have had their authorizations revoked by FDA. Current authorized PFAS applications for food contact materials do not degrade into PFOA or PFOS.[9]

---

[6] *See* National Council for Air and Stream Improvement, "Solid Residual Generation and Beneficial Use, and Wastewater Treatment Performance and Practices of the North American Pulp and Paper Industry," Technical Bulletin No. 1063, Cary, NC (Dec. 2019), Sec. 3.1, at p. 22.

[7] Paper mill residuals may also include boiler ash residuals and lime kiln residuals (mainly calcium carbonate and calcium oxide with trace amounts of magnesium, sulfur, boron and potassium). The makeup of land-applied mill residuals varies from mill to mill, and may also depend on the agronomic needs of the receiving land.

[8] See National Council of Air and Stream Improvement, "Solid residual generation and beneficial use, and wastewater treatment performance and practices of the North American pulp and paper industry," No. 1063 (Dec. 2019).

[9] USFDA 2022. Authorized Uses of PFAS in Food Contact Applications. Accessed October 28, 2022. https://www.fda.gov/food/chemical-contaminants-food/authorized-uses-pfas-food-contact-applications

More recently, AF&PA members have transitioned to PFAS-free alternatives and have virtually completed their voluntary transition out of FDA-approved short-chain PFAS. Currently, FDA-approved PFAS is used in less than 0.1% of AF&PA company members' total production.[10] AF&PA anticipates its members will entirely complete the ongoing transition out of FDA-approved short-chain PFAS by the end of 2023, if not sooner.

C. We Recommend that EPA Clarify the Preamble to Accurately Summarize the U.S. Paper Industry's Transition Out of PFAS

As drafted, the preamble does not accurately describe the pulp and paper industry's transition out of PFAS.[11] If EPA finalizes the rule, we request that the preamble be revised to accurately reflect our industry's timely and voluntary transition out of PFAS as outlined above.

II. The Final Rule Should Exclude PFOA and PFOS Contained in Paper Mill Residuals That Are Beneficially Applied to Land as a Fertilizer or Soil Conditioner.

A. Background on the Beneficial Land Application of Paper Mill Residuals

Papermill residuals can continue to be safely and beneficially applied to farmlands and forestlands.[12]

Many state programs require landowners receiving residuals to operate under management plans to ensure the safe and beneficial use of papermill residuals as soil amendments. These state regulated management plans often include:

- Chemical and physical characterization of the material
- Limits on application based on agronomically appropriate rates
- Restrictions on application in flooded or snow-covered fields
- Setbacks from streams, wells, and residential or public buildings
- Soil tillage and residuals incorporation requirements

[10] Based on information AF&PA collected in 2020, company member products containing intentionally added PFAS represented less than 0.1 percent of AF&PA members' paper and paperboard production.
[11] See 87 Fed. Reg. 54418-19 (outlining uses of PFAS in the U.S.).
[12] In addition, EPA should be mindful that residuals have value, and AF&PA members do not pay landowners to take our residuals.

- Siting and storage requirements[13]

Because the U.S. paper industry exited from its limited use of PFOA and PFOS in certain specialty products such as grease- and moisture-resistant packaging over a decade ago, the industry is not a source of new loadings into the environment above background concentrations. This is confirmed by data examined by AF&PA.

AF&PA reviewed samples of paper mill residuals which were tested for PFOA and PFOS. Many samples do not show detectable levels of PFOA or PFOS, but because PFOA and PFOS are widespread in the environment, they have been detected in some samples of paper mill residuals, albeit at very low levels. AF&PA data on paper mill residuals samples show median values of non-detect for PFOA and 4.05 parts per billion (ppb) for PFOS. This is below median values of PFOA and PFOS in many biosolids, and also below levels found in common household dust. For example, a study of PFOA and PFOS concentrations in biosolids by the Ecology Center and Sierra Club (2021) reports median concentrations of 1.53 ppb for PFOA and 13.2 ppb for PFOS.[14] Information on common house dust, which is often used as an environmental integrator of chemical deposition, and which we believe is representative of background contamination of PFOS, shows median values ranging from 24 ppb to 9 ppb for PFOA and 27 ppb to 4 ppb for PFOS for samples taken between 2013 and 2016.[15]

Because the manufacturing of PFOA and PFOS and their uses in many applications has been curtailed, their concentrations in the environment have declined over time. Because PFOA and PFOS concentrations in the environment have been trending downward over time, the sample collection timeframe is very important in making proper comparisons. For example, as provided by Hall et al., 2020, PFOS concentrations in common house dust for the period of 2000 to 2020 have declined by 98% from 201 ppb to 4 ppb. For PFOA, concentrations have declined by 94% in this same time frame,

---

[13] National Council for Air and Stream Improvement, "Guide to State-Specific Regulations on Beneficial Use of Manufacturing Residuals," Technical Bulletin No. 1064, Cary, NC (2019). We note that some states (e.g., Michigan) are developing risk management approaches that allow for land application of biosolids with de minimis levels of PFAS. *See* Michigan interim strategy on land application of biosolids (2021), available at https://www.michigan.gov/-/media/Project/Websites/egle/Documents/Programs/WRD/Biosolids/PFAS-Biosolids-Strategy.pdf?rev=c81c0064150d4f45bece88efcf304e3f

[14] PFA-Garden-Sludge-Report.pdf (sierraclub.org)

[15] Hall, SM, Patton, S, Petreas, M. et al., Per- and Polyfluoroalkyl Substances in Dust Collected from Residential Homes and Fire Stations in North America, Environ. Sci. & Tech, 2020, 54, 22. 14558-14567. Table in supplemental information: https://pubs.acs.org/doi/10.1021/acs.est.0c04869

from 142 ppb to 9 ppb (median values). Similar declining trends have been identified in other matrices.[16]

Accordingly, EPA can recognize the safe and beneficial application of paper mill residuals to promote plant growth on farmlands and forestlands without concern that doing so would increase environmental loadings of PFOA or PFOS.

B. The Listing of PFOA and PFOS in Table 302.4 Should Contain an Exclusion for PFOA and PFOS Contained in Beneficially Land-Applied Paper Mill Residuals.

1. The CERCLA Fertilizer Exclusion

When Congress enacted CERCLA in 1980, it provided four exclusions from the definition of "release," one of which is "the normal application of fertilizer."[17] EPA interpreted that exclusion in its preamble to the final Clean Water Act Part 503 standards for biosolids (then called "sewage sludge"). There, EPA said that the "normal application of fertilizer" encompasses application of municipal biosolids as a fertilizer or soil conditioner, if those biosolids meet applicable Part 503 standards.[18] Paper mill residuals are similarly used as a fertilizer or a soil conditioner, and PFOA and PFOS incidentally contained in such residuals should be similarly excluded from the scope of this rule. (We anticipate that municipalities and other entities interested in the continued land application of biosolids will seek a similar interpretation of the current biosolids exclusion for PFOA and PFOS contained in biosolids.[19]) As explained below, EPA has broad authority, relying on Congressional precedent, to incorporate such an exclusion in a listing rule under CERCLA Section 102(a).

2. CERCLA § 102(a) Grants EPA Broad Discretion to Create Exclusions from CERCLA Listings.

[16] Graber JM, Alexander C, Laumbach RJ, Black K, Strickland PO, Georgopoulos PG, Marshall EG, Shendell DG, Alderson D, Mi Z, Mascari M, Weisel CP. Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013-2014 NHANES. J Expo Sci Environ Epidemiol. 2019 Mar;29(2):172-182. doi: 10.1038/s41370-018-0096-z. Epub 2018 Nov 27. PMID: 30482936; PMCID: PMC6380951.
[17] 42 U.S.C. § 9601(22)(D).
[18] 58 Fed. Reg. 9248, 9262 (Feb. 19, 1993).
[19] *See, e.g.,* Rick Weber, "Lawyer Touts CERCLA Waivers for Biosolids as EPA Readies PFAS Rule," *Inside EPA* (Aug. 24, 2022).

Section 102(a) authorizes EPA to designate hazardous substances "as may be appropriate."[20] Congress's choice of words here gives EPA maximally broad discretion to determine the scope and conditions of any listing Section 102(a) regulation. The Supreme Court has stated that "'appropriate' . . . is 'open-ended' on its face,"[21] and that it "is the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors."[22] EPA therefore is authorized to take into account the facts, explained further below, that:

- Congress intended for the normal application of fertilizer to be excluded from CERCLA coverage;
- Paper mill residuals are used as a fertilizer or soil conditioner; and
- The Agency has previously found another form of wastewater treatment residuals, when land applied for this purpose, to fall within the CERCLA fertilizer exclusion.

EPA has never previously relied solely on its Section 102(a) authority to list a substance as a CERCLA hazardous substance. EPA therefore will be writing on a blank slate, exercising its full authority under that provision, unconstrained by any previous listing actions or statements regarding that authority. EPA should receive substantial deference for any Section 102(a) listings, moreover, as that subsection is a clear delegation of legislative rulemaking authority. Section 102(a) says: "The Administrator shall promulgate and revise as may be appropriate, regulations,"[23] and the Supreme Court has held that—

> [W]hen Congress grants an agency the authority to administer a statute by issuing regulations with the force of law, it presumes the agency will use that authority to resolve ambiguities in the statutory scheme. When Congress authorizes an agency to proceed through notice-and-comment rulemaking, that relatively formal administrative procedure is a very good indicator that Congress intended the regulation to carry the force of law….[24]

The breadth of EPA's authority under the "as may be appropriate" language of Section 102(a) applies equally to its ability to include substances within a listing and its ability to

---

[20] *See* 42 U.S.C. § 9602(a).
[21] *Tanzin v. Tanvir*, 141 S.Ct. 486, 491 (2020).
[22] *Michigan v. EPA*, 135 S.Ct. 2699, 2707 (2015)(internal quotations omitted).
[23] *See* 42 U.S.C. § 9602(a).
[24] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (2016)(internal citations and quotations omitted).

exclude them. The Supreme Court has concluded that Congress's use of the phrase "as provided for" in a provision of the Affordable Care Act, without "any [further] criteria or standards to guide" HHS,

> means that HRSA has *virtually unbridled discretion* to decide what counts as preventive care and screenings. But the same capacious grant of authority that empowers HRSA to make these determinations leaves its discretion equally unchecked in other areas, including the ability to *identify and create exemptions* from its own Guidelines.[25]

The phrase "as may be appropriate" certainly gives the Agency at least as much discretion as, if not more than, "as provided for." Therefore, EPA has the authority to provide, in a PFOA and PFOS listing, that PFOA and PFOS incidentally contained in paper mill residuals that are beneficially land-applied as a fertilizer or soil conditioner are excluded from that listing on the basis of the fertilizer exclusion.

3. Congress Contemplated that CERCLA Listings Could Have Exclusions

A Section 102(a) listing rule is just one of six ways that a material can become a CERCLA hazardous substance. The CERCLA definition of "hazardous substance," Section 101(14), has six subparagraphs. Subparagraph (B) refers to the Section 102(a) process. The five other subparagraphs -- (A), (C), (D), (E) and (F) – all refer to other lists created by EPA or Congress under different statutory authorities.[26] All current hazardous substances became so by being contained on one of those enumerated lists.

The metes and bounds of listings so incorporated into CERCLA provide guidance regarding what Congress envisioned for EPA's actions under Section 102(a), as EPA noted in the preamble.[27] The fact that Congress specifically designated these other listings to become hazardous substances by reference is prima facie evidence that EPA is free to incorporate any attribute of one of those listings into a listing under Section 102(a). So, for example, the presence of exclusions in many of the RCRA listed wastes and hazardous air pollutant descriptions that Congress designated as "hazardous

---

[25] *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S.Ct. 2367, 2380 (2020) (emphasis added).
[26] *See* 42 U.S.C. § 9601(14).
[27] *See* 87 Fed. Reg. 54423 ("CERCLA section 101(14) also includes CERCLA section 102(a), which suggests it should be interpreted in a manner similar to the other authorities on the list.").

substances" via Section 101(14)(C) and (E) indicates that Congress envisioned that hazardous substance listings – including those promulgated by EPA under Section 102(a) – can have exclusions. Certainly, to say that hazardous substances designated by Congress can have exclusions, but those designated by EPA under Section 102(a) cannot, would require some clear evidence of Congressional intent. But no such evidence exists. Thus, the presence of exclusions in the listings incorporated from RCRA and Clean Air Act, as discussed below, means that Congress contemplated that EPA's hazardous substance designations could also incorporate exclusions.

a. RCRA Listed Wastes

As just noted, CERCLA § 101(14)(C) incorporates RCRA listed wastes into the definition of "hazardous substance." Accordingly, the regulatory list of hazardous substances (40 C.F.R. § 302.4, Table 302.4) incorporates the RCRA F and K lists of hazardous wastes from non-specific and specific sources, respectively. These listings contain narratives that recite the conditions associated with these listings, many of which are complex. The descriptions of the F001 to F005 spent solvent listing are especially good examples. Each of these listings applies to an enumerated list of solvents, as well as to any spent solvent mixtures containing, before use, a total of 10% or more of one or more of those solvents and any of the solvents contained in any of the other F001-F005 solvent listings. For example, here is the description for F004:

> The following spent non-halogenated solvents: Cresols and cresylic acid, and nitrobenzene; all spent solvent mixtures/blends containing, before use, a total of ten percent or more (by volume) of one or more of the above non-halogenated solvents or those solvents listed in F001, F002, and F005; and still bottoms from the recovery of these spent solvents and spent solvent mixtures.[28]

So, under this example, a spent solvent mixture of cresol and seven other F-listed spent solvents, where, before use, each of them made up only 1% of the mixture, would not be a hazardous substance.[29]

b. CAA Hazardous air pollutants

[28] 40 C.F.R. § 261.31(a).
[29] The concentration cutoff was added to these listings in 1985 (*see* 50 Fed. Reg. 53316 (Dec. 31, 1985)), and hence was in place when Congress comprehensively amended CERCLA in 1986 – but Congress did not alter the statute to preclude it. Other RCRA listings that incorporate numerical cutoffs into the narrative include F024 & F025.

CERCLA Section 101(14)(E) incorporates Clean Air Act "hazardous air pollutants" (HAPs) into the definition of "hazardous substance." Many of these HAP listings also incorporate exclusions. For example, the "glycol ethers" listing has endnote "d," which among other things limits the associated radicals to alkyls of C7 or less.[30] So an alkyl C8 glycol ether would not be a hazardous substance. Similarly, the "polycyclic organic matter" listing has endnote "e," which excludes materials with a boiling point of less than 100° C. So polycyclic organic matter with a boiling point of 90° C would not be a hazardous substance. The Agency could adopt the same approach to implement an exclusion for PFOA and PFOS contained in paper mill residuals – the PFOA and PFOS listings could have their own endnote "g" that explains the exclusion.

4. If Need Be, EPA Can Limit the Exclusion to Cases Where PFOA and PFOS Are Present in Paper Mill Residuals at Concentrations Comparable to Concentrations in Other Fertilizers and Soil Conditioners

The Part 503 rules stated that biosolids fell within the fertilizer exclusion whenever they met permissible loading rates for nine metals and certain other management practices and operational standards.[31] While no EPA program sets standards for paper mill residuals comparable to those contained in the Part 503 rules, many state programs do set such standards, and EPA has commended such programs as "largely successful."[32]

The Part 503 rule does not currently contain standards for PFOA or PFOS. EPA is currently embarked on a multipathway risk assessment designed to serve as the basis for an update of the Part 503 standards, and this update could set standards for PFOA and PFOS, according to the Agency's *PFAS Strategic Roadmap*.[33] But the *Roadmap* does not project those standards to be issued until winter 2024, and a rulemaking on the topic is not even on the Long-Term Actions portion of EPA's Regulatory Agenda.[34] EPA still has two options, however, that would allow the continued beneficial land application of both biosolids and paper mill residuals:

---

[30] *See* 40 C.F.R. § 302.4, Table 302.4.
[31] 58 Fed. Reg. 9262.
[32] *See* 67 Fed. Reg. 48393 (July 24, 2002).
[33] *See* EPA, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024* (Oct. 18, 2021), at 16.
[34] *See* https://www.reginfo.gov/public/do/eAgendaHistory?operation=OPERATION_GET_PUBLICATION&showStage=longterm&currentPubId=202204.

- First, the final hazardous substance listings could simply exclude PFOA and PFOS contained in biosolids and paper mill residuals that are beneficially land applied as a fertilizer or soil conditioner, and EPA could reserve the right to set PFOA and PFOS levels at a future date.

- Second, the final listing rule could provide that PFOA and PFOS contained in biosolids and paper mill residuals that are beneficially land applied are excluded as constituting "the normal application of fertilizer" *whenever the levels of PFOA and PFOS in those materials are comparable to the levels found in the fertilizers for which they would be substituted.* This approach would be an application of the "identity principle," which EPA has relied on for forty years to define the limits of RCRA jurisdiction. Under this principle, waste-derived materials are not "solid wastes" when those materials contain hazardous constituents at levels that are "typical" for the commercial materials for which they are substituted.[35] EPA has applied this logic specifically in the case of fertilizers, excluding zinc fertilizers made from hazardous secondary materials from the definition of solid waste when their chemical makeup is "essentially identical" to that of zinc fertilizers made from virgin materials.[36] The ultimate basis of this logic is that "any potential risks posed by hazardous and non-hazardous zinc feedstock materials would be substantially similar."[37] This risk-based approach has been repeatedly upheld by the D.C. Circuit.[38]

Given the widespread presence of PFOA and PFOS in environmental matrices, EPA's exercise of one or the other of these options is necessary, as a practical matter, to avoid the unintended outcome of disrupting the established practices of land applying biosolids and paper mill residuals.[39]

5. Including the Fertilizer Exclusion in Rule Text would be a Logical Outgrowth of the Proposed Rule

[35] 67 Fed. Reg. 48393, 48402 (July 24, 2002).
[36] *See* 65 Fed. Reg. 70954, 70957 (Nov. 28, 2000).
[37] *Id*. at 70959.
[38] *See Safe Food and Fertilizer v. EPA*, 350 F.3d 1263, 1269-71 (D.C. Cir. 2003) (upholding the zinc fertilizer exclusion from the definition of solid waste); *American Petroleum Institute v. EPA*, 862 F.3d 50, 59-61 (D.C. Cir. 2017) (reaffirming the logic of *Safe Food* where constituent levels are "comparable").
[39] As a legal matter, EPA action is not necessary in order for beneficial land application of paper mill residuals and biosolids to fall within the fertilizer exclusion, since that exclusion is contained in the statute and can be construed by a court. *See Kelley v. United States*, 15 F.3d 1100, 1107 (1994). But EPA rulemaking on the topic would be vastly preferable, as it would hugely reduce the uncertainty and economic disruption that will otherwise flow from a hazardous substance listing of PFOA and PFOS.

EPA did not propose the exclusion we are requesting. But finalizing the exclusion would not violate the case law rule that a final rule must be a "logical outgrowth" of the proposed rule. The basic formulation of the logical outgrowth standard asks whether "interested parties could . . . reasonably have anticipated the final rulemaking from the [proposal]."[40] Here, EPA has proposed a broadly inclusive listing under a statute that incorporates multiple broad, well-known exclusions, including the fertilizer exclusion and the petroleum exclusion. Interested persons can reasonably anticipate that affected entities will ask EPA to implement those exclusions in the final rule. Water systems, for example, have been actively advocating for an exemption from any CERCLA listing.[41] Codifying the fertilizer exclusion into the CERCLA listing would not be the Agency "completely chang[ing] its position"[42] or "abandoning [its] proposed regulatory approach."[43]

Notably in this context, the Supreme Court's first decision adopting the logical outgrowth test involved an agency finalizing an exemption that was not contained in the proposal. In *Long Island Care at Home, Ltd. v. Coke*,[44] the Labor Department borrowed an exemption from minimum wage and maximum hour requirements and extended it to "companionship services" supplied by third-party agency employees:

> Since the proposed rule was simply a proposal, its presence meant that the Department was *considering* the matter; after that consideration the Department might choose to adopt the proposal or to withdraw it. As it turned out, the Department did withdraw the proposal for special treatment of employees of "covered enterprises." The result was a determination that exempted *all* third-party-employed companionship workers from the Act. We do not understand why such a possibility was not reasonably foreseeable.[45]

Finally, the fact that comments such as these urge EPA to create an exclusion in the listing shows that the issue is reasonably foreseeable:

---

[40] *See Nat'l Ass'n of Mfrs. v. MSHA*, 116 F.3d 520, 531 (D.C. Cir. 1997).
[41] *See* "Lawyer Touts CERCLA Waivers for Biosolids as EPA Readies PFAS Rule," *supra*; *see also* letter from water sector associations to congressional committee leadership re "Necessity of Protecting Water Systems from CERCLA Liability for PFAS" (April 28, 2022), available at https://www.nacwa.org/docs/default-source/resources---public/cercla-water-system-hill-letter-4-28-22.pdf?sfvrsn=4dfcc461_2.
[42] *CSX Transportation, Inc. v. Surface Transportation Board*, 584 F.3d 1076, 1081 (D.C. Cir. 2009).
[43] *Int'l Union, United Mine Workers of Am. v. MSHA*, 407 F.3d 1250, 1260 (D.C. Cir. 2005).
[44] 551 U.S. 158 (2007).
[45] *Id.* at 175 (emphasis in original).

> Numerous commenters — including two that are among the Industry Petitioners here — filed comments that were critical of the distinction between refractory and nonrefractory units. On the other side, Northeast Maryland's predecessor, WEP, filed comments that supported the distinction. Accordingly, we reject Northeast Maryland's contention that the evolution of the rule deprived it of adequate notice and an opportunity to comment.[46]

Accordingly, EPA should not feel constrained from implementing the requested exclusion in the CFR text of the listing descriptions.

6. Incorporating Exclusions into the CERCLA Listings is not "Exemp[ting] Particular Entities from Liability"

Slide 6 of EPA's slides for its presentation to the Small Business Administration's Environmental Roundtable meeting on October 7, 2022, says: "EPA does not have authority to exempt particular entities from liability." *That is not what we are asking*.

EPA's statement is no doubt motivated by *Kelley v. United States*,[47] a prominent decision by the D.C. Circuit declaring that courts, not EPA, get to determine liability under CERCLA. The case involved EPA's 1992 lender liability rule, which exempted lenders from owner or operator liability under certain circumstances. As statutory authority to issue that rule, the Agency pointed to its "housekeeping" authorization in Section 115, general language in CERCLA Section 105 about EPA's authority "to reflect and effectuate the responsibilities and powers created by" CERCLA, aspects of Section 107, and the reimbursement provisions of Section 106.[48] The court disagreed, holding broadly that none of these provisions gave EPA "authority to, by regulation, define liability for a class of potential defendants."[49]

But we are not asking EPA to issue a liability exemption rule under Section 107 (or any other section of CERCLA). To be precise, we are asking EPA, in a hazardous substance listing rule under Section 102(a), to exclude, from the regulatory listing of PFOA and PFOS in Table 302.4 of the CERCLA regulations, PFOA and PFOS under certain circumstances, i.e., when they are contained in paper mill residuals that are beneficially land applied as a fertilizer or soil conditioner. As explained above, unlike all the CERCLA

[46] *North East Maryland Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004) (citations omitted).
[47] 15 F.3d 1100 (D.C. Cir. 1994).
[48] *Id*. at 1105-1106.
[49] *Id.* at 1107.

provisions invoked in *Kelley*, Section 102(a) *does* present "explicit . . . evidence of congressional intent to delegate interpretive authority:"[50] Its authorization that EPA "shall promulgate and revise as may be appropriate, regulations designating as hazardous substances"[51] gives EPA clear authority to exclude PFOA and PFOS from a listing regulation when they are contained in paper mill residuals that are beneficially land applied.

C. At a Minimum, the Preamble of the Final Rule Should Announce EPA's Interpretation of the Fertilizer Exclusion as Excluding PFOA and PFOS When Either Is Contained in Paper Mill Residuals That Are Beneficially Land Applied as a Fertilizer or Soil Conditioner.

As noted earlier, the preamble to the 1993 Part 503 standards for biosolids announced EPA's interpretation of the fertilizer exclusion to provide that land application of municipal biosolids as a fertilizer or soil conditioner is not a release of hazardous substances, if the biosolids meet enumerated specifications:

> Today's rule, as previously noted, establishes standards for sewage sludge when applied to the land for a beneficial purpose (i.e., as a fertilizer substitute or soil conditioner). Sludge placed on the land for such beneficial purpose and applied in compliance with the requirements for land application of sewage sludge provided in §§ 503.13(b) (2) and (4), § 503.14 and § 503.15 (where applicable) of the final rule today, and in accordance with accepted agricultural practices using appropriate application rates, which constitutes the normal application of fertilizer, does not constitute a "release."[52]

EPA reiterated this interpretation a year later (and after issuance of the *Kelley* decision), in its "Plain Language Guide to the EPA Part 503 Biosolids Rule":

> Landowners (including their lenders) and leaseholders who use biosolids beneficially as a fertilizer substitute or soil conditioner in accordance with EPA's Part 503 rule are protected from liability under the Superfund legislation (Comprehensive Environmental Response, Compensation and Liability Act-CERCLA) (see 58 Federal Register 9262, February 19, 1993) as well as any enforcement action from EPA under the Part 503 rule. Where the Federal

[50] *Id*. at 1105, quoting *Linemaster Switch Corp. v. EPA*, 938 F.2d 1299, 1303 (D.C. Cir. 1991).
[51] 42 U.S.C. § 9602(a).
[52] 58 Fed. Reg. 9262.

> requirements are not followed, appliers of biosolids are vulnerable to EPA enforcement actions or citizen-initiated suits and can be required to remediate any problems for which they are found liable. [53]

It would be far better, for multiple reasons, if the final C.F.R. text in this rulemaking were to contain an exclusion for PFOA and PFOS contained in paper mill residuals that are beneficially land applied. If EPA does not do that, the Agency can and should follow the precedent of the Part 503 rules and propound our recommended exclusion in the preamble to final rule, as an interpretation of the fertilizer exclusion. If necessary, EPA could limit the exclusion to cases where PFOA and PFOS are present at concentrations in the residuals comparable to biosolids and other fertilizers and soil conditioners.

As an interpretive rule, this interpretation would be entitled to deference – as *Kelley* noted, EPA is free to issue interpretive rules, "based on specific statutory provisions [of CERCLA,] represent[ing] the agency's construction of the statute."[54]

III. Section 102(a) Requires Consideration of Costs in Making the Listing Decision.

EPA claims that Section 102(a) "precludes" the Agency from considering costs in promulgating hazardous substance listings. It first evaluates the text of the statute in light of relevant case law, and then looks for illumination among the five other statutory provisions cross-referenced in the CERCLA definition of "hazardous substance."[55] As shown below, EPA misconstrues both of these sources of authority. In fact, to the contrary, the statutory text and Supreme Court precedent *require* EPA to consider costs. So did at least one of the other statutory provisions at the time of CERCLA's enactment, while another allowed it, then and now.

A. In Light of Supreme Court Case Law, Section 102(a)'s Use of "Appropriate" Requires EPA To Consider Costs in Designating Hazardous Substances

[53] *See* EPA/832/R-93/003 (Sept. 1994), at 52-53. Available at https://www.epa.gov/sites/production/files/2018-12/documents/plain-english-guide-part503-biosolids-rule.pdf.
[54] *See* 15 F.3d at 1107-1108.
[55] *See* 87 Fed. Reg. at 54421-54423.

Under a line of cases from *State Farm*[56] to *Entergy Corp. v. Riverkeeper, Inc.* [57]to *Michigan v. EPA*,[58] agencies must weigh cost and benefits in setting regulatory standards, absent explicit statutory text to the contrary.[59]

Nothing in the language of Section 102(a) precludes EPA from considering cost. To the contrary, by directing EPA to promulgate or revise designations of hazardous substances "as may be appropriate," that provision requires EPA to consider costs. In *Michigan v. EPA,* the Supreme Court declared that "appropriate" is the kind of "capacious" language that requires the consideration of all relevant factors, including cost. As the *Michigan* majority concluded, in construing statutory language requiring EPA to regulate where "appropriate and necessary," "no regulation is 'appropriate' if it does significantly more harm than good."[60] Indeed, all nine justices in *Michigan* agreed that "[c]ost is almost always a relevant—and usually, a highly important—factor in regulation. Unless Congress provides otherwise, an agency acts unreasonably in establishing 'a standard-setting process that ignore[s] economic considerations.'"[61] The preamble to the proposed rule omits "appropriate" the first two times it paraphrases the statute.[62] But on page 54422, the preamble concedes that Section 102(a) "does use the word 'appropriate.'"

As the *Michigan* majority explained, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages *and* disadvantages of agency decisions."[63] Under multiple executive orders issued by the previous two Democratic presidents, for any rulemaking, the agency must ensure that (i) the benefits of the rule justify the costs and (ii) the rule maximizes net benefits, "to the extent permitted by law."[64] Agencies must "tailor [their] regulations to impose the least burden on society, . . . taking into account . . . the costs of cumulative regulations."[65] The Office of Information and Regulatory Affairs in the White House Office of Management and Budget required EPA to designate this rulemaking as

---

[56] *Motor Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29 (1983).
[57] 556 U.S. 208 (2009).
[58] 135 S.Ct. 2699 (2015).
[59] The development of this requirement through the Court's caselaw is thoroughly documented in Paul R. Noe and John D. Graham, "The Ascendancy of the Cost-Benefit State?," 5 ADMIN. L. REV. *ACCORD* 85 (2020).
[60] 135 S.Ct. at 2707.
[61] *Id*. at 2716-2717 (Kagan, J., dissenting).
[62] *See* 87 Fed. Reg. 54415, 54420-54421.
[63] 135 S.Ct. at 2707 (emphasis in original).
[64] *See* E.O. 12866, §§ 1(a) & (1(b)(6); E.O. 13563, § 1(b).
[65] E.O. 13565, § 1(b).

economically significant, triggering the additional requirement that EPA (i) prepare and consider a cost-benefit analysis and (ii) consider potentially effective and reasonably feasible alternatives.[66] Paraphrasing the *Michigan* majority opinion, "[a]gainst the backdrop of this established administrative practice, it is unreasonable to read an instruction to an administrative agency to determine whether [regulating a substance as a hazardous substance is 'appropriate'] as an invitation to ignore cost."[67]

EPA says "the word 'appropriate' is not used in the context of what EPA should consider when assessing whether a substance is hazardous."[68] That is true – the word "appropriate" is used in the context of *whether EPA should "designate" a substance under CERCLA Section 102(a)* — the ultimate issue in this rulemaking.[69] As shown above, EPA is required to consider costs in determining whether to make that designation.

The preamble for the proposed rule does not address the potential impact of the hazardous substances designations on biosolids or mill residuals, nor does it analyze the questions on the impact of the proposed designations on municipal biosolids or mill residuals. If the designation created significant stigma and perceived risk about continuing to use mill residuals as soil amendments, and mill residuals were sent to Subtitle C landfills, the impacts could be very substantial. For example, an economic analysis prepared for AF&PA indicates that the potential cost for the paper industry, including potential need to send mill residuals to Subtitle C landfills and a potential need to construct landfills at paper mills, could be: (1) in a moderate case, $300 million in operating costs per year, $2.2 billion in capital costs for construction of landfills, and $573 million amortized annually; and (2) in a worst case, $366 million in operating costs per year, $3.3 billion in capital costs, and $776 million amortized annually. This potentially could jeopardize high-paying mill jobs well above the prevailing wage in small rural communities – without providing an appreciable benefit.

In addition to this unnecessary and severe economic impact, the designations could have serious environmental and health costs. For example, one unintended outcome could be to significantly overburden currently available and future landfill capacities for material that provides a safe and beneficial soil amendment. Transporting these materials to Subtitle C hazardous waste sites also potentially could require a huge effort,

---

[66] *Id.* § 6(a)(3)(C).
[67] 135 S.Ct. at 2708.
[68] 87 Fed. Reg. 54423.
[69] *See* 42 U.S.C. § 9602(a) ("The Administrator shall promulgate and revise as may be *appropriate*, regulations *designating* as hazardous substances . . . .")(emphasis added).

on the order of 250,000 dump trucks (carrying 20 tons each) traveling 500 miles each year. The result could be a significant increase in emissions of greenhouse gases and conventional air emissions, as well as increased vehicle accident risks and more traffic in disadvantaged communities. Given current truck driver shortages, this also could disrupt the supply chain.

B. The Five Statutory Provisions Listed in the CERCLA Definition of "Hazardous Substance" Do Not Uniformly Preclude Consideration of Costs

In arguing that Section 102(a) precludes consideration of costs, EPA claims that the five statutory provisions cross-referenced in CERCLA's definition of "hazardous substance" (42 U.S.C. § 9601(14)(A), (C), (D), (E), and (F)) preclude consideration of costs. EPA claims that "[u]nder the other statutory provisions, that program's compliance costs are not considered a factor or criteria in making listing decisions . . . ."[70] Both statements are incorrect.

1. TSCA Section 7

Costs *were* relevant under Section 7 of the Toxic Substances Control Act (TSCA) as it stood in 1980, when CERCLA was enacted. That section then defined an "imminently hazardous chemical substance or mixture" as one that "present[ed] an imminent *and unreasonable* risk of serious or widespread injury to health or the environment."[71] "Imminent" was further defined as "likely to result in injury to health or the environment before a final rule *under section 2605* of this title can protect against such risk."[72] Section 2605 was (and still is) the mechanism by which EPA can take action against substances posing "unreasonable risk." In 1980, for EPA to issue a rule concluding that a substance presented "unreasonable risk," EPA had to consider "the reasonably ascertainable economic consequences of the rule."[73] So an "imminently hazardous substance or mixture" in 1980 was one that posed an unreasonable risk, taking into account the costs of regulating that risk. CERCLA Section 101(14)(F) thus does not demonstrate congressional intent to prevent EPA from considering costs under Section 102(a).

[70] 87 Fed. Reg. 54423.
[71] 15 U.S.C. § 2606(f) (1976) (emphasis added).
[72] *Id.* (emphasis added).
[73] *Id.* § 2605(c)(1)(D) (1976).

2. CWA Section 311(b)(2)(A)

Congress obviously modeled CERCLA Section 102(a) very closely on Clean Water Act (CWA) Section 311(b)(2)(A), which provides that "[t]he Administrator shall develop, promulgate, and revise as may be appropriate, regulations designating hazardous substances . . . ." That provision also does not preclude consideration of costs when EPA designates substances under it. To the contrary, in interpreting this precedential provision, EPA has determined that it is "appropriate" for the Agency to consider factors beyond toxicity, including cost, when deciding whether to list or delist a substance under CWA Sec. 311(b)(2)(A). In fact, EPA did this in *the original 1978 implementing regulations for that provision*. After developing an initial list of substances meeting the CWA Section 311 toxicity criteria, EPA screened that list down "to a practical number" based on "discharge potential," as determined by a number of factors, including the "cost of the substance."[74]

EPA likewise considered costs in a rulemaking removing ammonium thiosulfate from both the CWA and CERCLA hazardous substance listings in 1989. Two features of this rulemaking are notable. First, EPA evaluated the ammonium thiosulfate listing under both the CWA *and CERCLA*, contrary to EPA's claim that, "[w]hen EPA adds a substance or chemical for regulation under any of those other statutory provisions, it also becomes a CERCLA hazardous substance --without considering the resulting costs under CERCLA."[75] As the preamble made clear, EPA evaluated the delisting under both statutes:

> EPA agrees with the commenters that ammonium thiosulfate does not meet the [CWA 311] listing criteria for aquatic toxicity. In addition, the Agency has analyzed ammonium thiosulfate under the primary criteria other than aquatic toxicity and determined that there is no independent basis for listing this substance as hazardous under CERCLA section 102.[76]

Second, EPA expressly considered costs in that joint CWA/CERCLA rulemaking. After noting that the substance did not meet applicable toxicity criteria, the Agency noted that "[f]ive commenters stated that the current classification of ammonium thiosulfate

[74] *See* 43 Fed. Reg. 10474, 10474-10475, 10478 (March 13, 1978).
[75] 87 Fed. Reg. 54423.
[76] 54 Fed. Reg. 33441.

as a hazardous substance has resulted in increased insurance costs to transport this substance."[77]

CERCLA Section 101(14)(A) thus does not demonstrate congressional intent to prevent EPA from considering costs under Section 102(a).

Accordingly, EPA is not uniformly prohibited from considering costs under the other provisions listed in the CERCLA definition of "hazardous substance," most notably the one on which CERCLA Section 102(a) was modeled.

IV. Even if EPA Were Not Required to Consider Costs in Promulgating Section 102 Hazardous Substance Listings, the Agency Has Discretion to Do So – And Must Explain Its Decision Making on That Point

At a minimum, Congress' use of "appropriate" in § 102(a), in light of case law, means that EPA possesses discretion to consider costs in designating hazardous substances under that authority. In *Entergy Corp. v. Riverkeeper, Inc.*, the Supreme Court construed a provision of the Clean Water Act requiring that a class of cooling water intake structures "reflect the best technology available for minimizing adverse environmental impact" to determine whether that language allowed EPA to base standards in part on a cost-benefit analysis, as the Agency contended, or prohibited it, as the petitioner environmental groups argued. Finding the provision to be silent on the topic, the Court agreed with EPA, declaring that "[i]t is eminently reasonable to conclude that § 1326(b)'s silence is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree."[78]

Even assuming, arguendo, that "appropriate" did not require consideration of costs in this rulemaking, it at least would allow it. That conclusion is supported by the D.C. Circuit's recent decision in *Utility Solid Waste Action Group v. EPA*, which addressed whether RCRA Subtitle D authorizes EPA to consider costs in rulemakings under it. In declining to adopt that construction, the court said: "Nor is there any flexible language such as 'appropriate and necessary' that might allow EPA to consider costs in its rulemaking."[79] Here, there is exactly such language.

[77] *See* 54 Fed. Reg. 33426, 33441 (Aug. 14, 1989).
[78] 556 U.S. 208, 222 (2009).
[79] 901 F.3d 414, 449 (D.C. Cir. 2018).

Further, as noted above, of the five other statutory provisions listed in the CERCLA definition of "hazardous substance," one of them required EPA to consider costs in listing chemicals under it at the time CERCLA was enacted, and another – the model for Section 102(a) – permitted consideration of costs then and still does.

At a minimum, therefore, EPA possesses discretion to consider costs when it makes a designation of PFOA or PFOS under Section 102(a). Cost is a highly relevant and important factor in deciding whether it is "appropriate" to list PFOA and PFOS as hazardous substances, with far-reaching economic consequences. It would be arbitrary and capricious for EPA to finalize such a designation without providing a reasoned explanation of how and why it exercised that discretion. That is particularly the case now that comments such as these have teed up the issue.[80] In that respect, this rulemaking bears an uncanny similarity to the fuel economy standards at issue in *Center for Biological Diversity v. National Highway Traffic Safety Administration* (NHTSA).[81] In that case, the court "agree[d] with NHTSA that EPCA neither requires nor prohibits the setting of standards at the level at which net benefits are maximized[, and thus] that NHTSA has discretion to balance the oft-conflicting factors in [the statute] when determining "maximum feasible" CAFE standards."[82] Nonetheless, the court added: "We must still review whether NHTSA's balancing of the statutory factors is arbitrary and capricious."[83] The court then concluded that NHTSA had acted arbitrarily and capriciously, undervaluing benefits while overvaluing costs, and by assigning no value to carbon emissions benefits that clearly existed, albeit in a range, while quantifying other benefits.[84] Similarly, the court struck down NHTSA's decision not to close the "SUV loophole," holding that, while "the Secretary has discretion to decide what constitutes a 'passenger automobile,'" "NHTSA has not provided a reasoned explanation of why an orderly transition to Reformed CAFE could not be accomplished at the same time that the passenger automobile/light truck definitions are revised."[85] EPA has the opportunity to avoid NHTSA's fate by providing a reasoned explanation of how it exercised its discretion to consider costs in this rulemaking.

Conclusion

[80] *See Encino Motorcars*, 136 S.Ct. at 2126.
[81] 538 F.3d 1172 (9th Cir. 2008).
[82] 538 F.3d at 1197.
[83] *Id*.
[84] Id. at 1194-1198.
[85] *Id*. at 1206-1209.

AF&PA appreciates the opportunity to submit these comments on EPA's proposed rule to list PFOA and PFOS as hazardous substances under CERCLA. We thank you for your careful consideration of them. If you have questions or need more information, please feel free to contact me at 202-463-2700 or Paul_Noe@afandpa.org.

Best regards,

Paul Noe
Vice President for Public Policy

cc: Barry Breen, Acting Assistant Administrator, OLEM
Carlton Waterhouse, Deputy Assistant Administrator, OLEM
Deborah Nagle, Director, OST, OW
Jen Lewis, Deputy Associate General Counsel, OGC
Victoria Arroyo, Associate Administrator, OP
Barry Elman, Acting Program Manager, Smart Sectors Program, OP
Al McGartland, Chief Economist, OP

November 7, 2022

Via Regulations.gov

Mr. Barry Breen
Acting Assistant Administrator, Office of Land and Emergency Management
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

Re: Comprehensive Environmental Response, Compensation, and Liability Act Hazardous Substances: Designation of Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid, Docket No. EPA–HQ–OLEM–2019–0341

Dear Mr. Breen:

The undersigned organizations submit these comments in strong support of the U.S. Environmental Protection Agency's ("EPA") proposed designations of perfluorooctanoic acid ("PFOA") and perfluorooctanesulfonic acid ("PFOS") as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA").[1] Our organizations include communities contaminated by PFOA and PFOS; scientists who study the harms associated with PFOA, PFOS, and other per- and polyfluoroalkyl substances ("PFAS"); and advocates for strengthened federal, state, and local protections against PFAS.

PFOA and PFOS are two of the most pervasive members of the PFAS class, which comprises thousands of chemicals that have contaminated drinking water supplies for nearly two out of every three people in the United States. While EPA has known of the risks posed by PFOA and PFOS for decades—including multiple types of cancer, liver disease, autoimmune disorders, and other serious harms—these chemicals remain unregulated under CERCLA and most other federal environmental laws. The absence of CERCLA hazardous substance designations has impeded the treatment and remediation of PFAS by making it harder for impacted communities to identify releases and to recover their clean-up costs from responsible parties. When releases are not timely reported and remediated, PFAS contamination spreads faster than it can be detected, leaving more communities exposed to these toxic chemicals and placed at greater risk.

We support the proposed hazardous substance designations, which would notify the government of PFOA and PFOS releases and facilitate the remediation of contaminated soil, sediment, surface water, and groundwater. We urge EPA to promptly finalize those designations with certain modifications, set forth below, that promote "the timely cleanup of [contaminated] sites," which is a "fundamental purpose and objective of CERCLA."[2]

[1] Proposed Rule, Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances, 87 Fed. Reg. 54,415 (Sept. 6, 2022).
[2] *Fireman's Fund Ins. Co. v. City of Lodi*, 302 F.3d 928, 947 (9th Cir. 2002).

A. PFOA and PFOS Satisfy the Standard for Designation as Hazardous Substances

CERCLA authorizes EPA to "designat[e] as hazardous substances . . . such . . . substances which, when released into the environment may present substantial danger to the public health or welfare or the environment."[3] As EPA correctly found in its proposed hazardous substance designations, PFOA and PFOS meet that listing standard.[4]

PFAS, including PFOA and PFOS, "are an urgent public health and environmental issue facing communities across the United States."[5] PFAS are highly persistent chemicals that have contaminated the water supplies for more than 200 million Americans and the air, soil, and food supplies of countless others.[6] A century ago, PFAS did not exist; today, they are present in the blood of more than 98% of the U.S. population.[7] Many PFAS, including PFOA and PFOS, bioaccumulate in animals and people, meaning even low exposures build up into higher concentrations in people's bodies. Exposure to PFOA, PFOS, and many other PFAS are associated with a range of serious harms, including cancer, developmental and reproductive harm, liver disease, and other health effects.[8]

---

[3] 42 U.S.C. § 9602(a).

[4] 87 Fed. Reg. at 54,424–29.

[5] EPA, *PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024*, at 5 (2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf ("PFAS Roadmap"); *see also id.* at 1 (describing EPA's plans to "to restrict these dangerous chemicals from getting into the environment").

[6] *See* Annie Sneed, *Forever Chemicals Are Widespread in U.S. Drinking Water*, Sci. Am. (Jan 22, 2021), https://www.scientificamerican.com/article/forever-chemicals-are-widespread-in-u-s-drinking-water/.

[7] Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003-2004 and Comparisons with NHANES 1999-2000*, 115 Env't Health Perspectives 1596 (2007), http://doi.org/10.1289/ehp.10598.

[8] *What Are the Health Effects of PFAS?*, Agency for Toxic Substances and Disease Registry, https://www.atsdr.cdc.gov/pfas/health-effects/index.html (last updated Sept. 9, 2022).

The risks from PFOA and PFOS are well established and broadly recognized by international organizations,[9] federal and state regulatory agencies,[10] and leading scientific bodies.[11] EPA recently conducted updated toxicity assessments for both of those chemicals, which found that they harm children's immune systems and reduce vaccine effectiveness at extremely low exposure levels, in the parts-per-quadrillion range.[12] Those assessments were based on EPA's review of hundreds of studies that were published since 2013. Because those studies identified health risks below most laboratories' detection limits for PFOA and PFOS, EPA warned that "any detectable level of PFOA [and] PFOS" places children's health at risk.[13] Therefore, particularly when the chemicals' persistence, mobility, and capacity for bioaccumulation are taken into account, any release of PFOA and PFOS "may present substantial danger to the public health or welfare or the environment."[14]

As EPA noted, a finding that a substance "may present" substantial danger "d[oes] not require certainty that the substance presents a substantial danger or require proof of actual harm."[15] Here, however, the dangers associated with PFOA and PFOS are not merely predicted or hypothetical; they are being experienced in communities across the country. For example,

---

[9] *See* United Nations Env't Programme, UNEP/POPS/POPRC.2/17/Add.5, *Report of the Persistent Organic Pollutants Review Committee on the Work of Its Second Meeting* add. 25–26 (Nov. 2006) (Risk Profile on Perfluorooctane Sulfonate), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.2-17-Add.5.English.PDF; United Nations Env't Programme, UNEP/POPS/POPRC.12/11/Add.2, *Report of the Persistent Organic Pollutants Review Committee on the Work of Its Twelfth Meeting* add. 24–26 (Oct. 2016) (Risk Profile on Pentadecafluorooctanoic Acid (PFOA, Perfluorooctanoic Acid), Its Salts and PFOA-related Compounds), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.12-11-Add.2.English.PDF.

[10] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls* 7–21 (May 2021), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; Cal. Env't Protection Agency, First Public Review Draft, *Public Health Goals*: *Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water* (July 2021) https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.

[11] Nat'l Acads. of Scis., Eng'g, & Med., *Guidance on PFAS Exposure, Testing, and Clinical Follow-Up* 7–8 (2022), https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up.

[12] EPA, EPA/822/R-22/003, *Interim Drinking Water Health Advisory: Perfluorooctanoic Acid (PFOA) CASRN 335-67-1*, at 10 (June 2022), https://www.epa.gov/system/files/documents/2022-06/interim-pfoa-2022.pdf; EPA, EPA/822/R-22/004, *Interim Drinking Water Health Advisory: Perfluorooctane Sulfonic Acid (PFOS) CASRN 1763-23-1*, at 11 (June 2022), https://www.epa.gov/system/files/documents/2022-06/interim-pfos-2022.pdf.

[13] EPA, EPA/822/F-22/002, *Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX Chemicals, and PFBS)* 5 (June 2022), https://www.epa.gov/system/files/documents/2022-06/technical-factsheet-four-PFAS.pdf.

[14] 42 U.S.C. § 9602(a).

[15] 87 Fed. Reg. at 54,421.

epidemiological studies of nearly 70,000 people in and around Parkersburg, WV, where DuPont manufactured and released PFOA, found that people who were exposed to PFOA had higher rates of thyroid disease, autoimmune disease, high cholesterol, testicular and kidney cancer, and pregnancy-induced hypertension.[16] Other studies of people who were exposed to PFOS detected similar results.[17] EPA was thus correct to conclude that the evidence that PFOA and PFOS pose substantial dangers to public health and the environment is "more than sufficient to satisfy the CERCLA section 102(a) standard."[18]

B. EPA Correctly Interpreted CERCLA to Preclude the Consideration of Costs in Hazardous Substance Designations

In its proposed rule, EPA correctly "interpret[ed] the language of CERCLA section 102(a) as precluding the Agency from taking cost into account in designating hazardous substances."[19] EPA also solicited comment on that interpretation.[20] We support EPA's construction and application of CERCLA section 102(a), which accords with CERCLA's unambiguous text, statutory structure, and judicial interpretations of comparable provisions of other environmental laws.

"Statutory interpretation starts—and often ends—with the text of the statute," which is "generally deemed to carry [its] plain and ordinary meaning."[21] CERLA's text contains a single criterion for the designation of a hazardous substance: whether the substance, "when released into the environment[,] may present substantial danger to the public health or welfare or the environment."[22] That provision requires EPA to make listing determinations based solely on the "danger" that the release of a substance poses to public health, welfare, or the environment—not on the economic value of the substance or the costs that may flow from such a designation. The ordinary meaning of "danger," in the context of a hazardous substance release, is "the possibility of harm or death."[23] Compliance costs do not constitute "substantial danger to the public health

[16] *C8 Probable Link Reports*, C8 Sci. Panel, http://www.c8sciencepanel.org/prob_link.html (last visited Nov. 1, 2022).
[17] Bos. Child.'s Hosp. Pediatric Env't Health, *Poly- and Perfluoroalkyl Substances (PFAS) – Emerging Pollutants in New England: A White Paper* 3 (2020), https://www.hsph.harvard.edu/niehs-dev/wp-content/uploads/sites/2603/2021/04/PEPH-version-2020-New-England-PEHSU-PFAS-guide1-27-21-2-22-21-4-2-21.pdf.
[18] 87 Fed. Reg. at 54,417.
[19] *Id.* at 54,421.
[20] *Id.* at 54,423.
[21] *In re Shamus Holdings, LLC*, 642 F.3d 263, 265 (1st Cir. 2011); *see also Good Samaritan Hosp. v. Shalala,* 508 U.S. 402, 409 (1993) ("The starting point in interpreting a statute is its language, for [i]f the intent of Congress is clear, that is the end of the matter." (alteration in original) (quotation omitted)); *Wilson v. United States*, 6 F.4th 432, 435 (2d Cir. 2021) ("In interpreting any statute, we start with the plain meaning of the text, and absent any ambiguity, we end there too.").
[22] 42 U.S.C. § 9602(a).
[23] *Danger*, Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/danger (last visited Nov. 1, 2022).

or welfare or the environment," and they are not attributable to the "release[]" of a hazardous substance into the environment,[24] but rather to EPA's separate act of designating the substance as hazardous. EPA thus properly concluded that "Congress did not list cost as a required or permissible factor, and none of the Congressionally-listed statutory factors encompass a consideration of cleanup costs."[25]

In contrast to the provision governing hazardous substance designations, other parts of CERCLA authorize or require the consideration of costs when making remedial decisions. For instance, when "establish[ing] procedures and standards for responding to releases of hazardous substances, pollutants, and contaminants," Congress directed EPA to consider, among other factors, whether the "remedial action measures are cost-effective over the period of potential exposure to the hazardous substances."[26] Similarly, when evaluating proposed remedial options for a given site, CERCLA authorizes EPA to "take into account the total short- and long-term costs of such actions, including the costs of operation and maintenance for the entire period during which such activities will be required."[27] The express authorization to consider costs in other CERCLA provisions further supports EPA's interpretation of section 102(a), since "when Congress includes particular language in one section of a statute but omits it in another," an agency must "'presume' that Congress intended a difference in meaning."[28]

EPA's position also is supported by judicial interpretations of health-focused provisions of other environmental laws, which have also been interpreted to exclude the consideration of costs. For instance, the Clean Air Act requires EPA to set national ambient air quality standards at levels "requisite to protect the public health" with "an adequate margin of safety."[29] Construing this "absolute" language, the Supreme Court found it "fairly clear that this text does not permit the EPA to consider costs in setting the standards."[30] Similarly, under the Resource Conservation and Recovery Act ("RCRA"), EPA may classify a disposal facility as a "sanitary landfill," which is subject to less stringent regulatory requirements than an "open dump," only if "there is no reasonable probability of adverse effects on health or the environment from disposal of solid waste at such facility."[31] Under that statute as well, the D.C. Circuit Court of Appeals held that EPA was not required to consider costs in its analysis of "adverse effects on health or

[24] 42 U.S.C. § 9602(a).
[25] 87 Fed. Reg. at 54,421.
[26] 42 U.S.C. § 9605(a), (a)(7).
[27] *Id.* § 9621(a); *see also id.* § 9621(b) ("The President shall select a remedial action that is protective of human health and the environment [and] that is cost effective . . . .").
[28] *Loughrin v. United States*, 573 U.S. 351, 358 (2014) (quotation and alteration omitted); *Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").
[29] 42 U.S.C. § 7409(b)(1).
[30] *Whitman v. Am. Trucking Ass'ns,* 531 U.S. 457, 465 (2001) (quotation omitted).
[31] 42 U.S.C. § 6944(a).

the environment" and that it was "far from clear that the EPA could consider costs even if it wanted to."[32] Finally, the Toxic Substances Control Act ("TSCA") requires EPA to "identify . . . lead-based paint hazards,"[33] which are defined as "any condition that causes exposure to lead . . . that would result in adverse human health effects."[34] The Ninth Circuit Court of Appeals held that EPA could not consider costs when establishing such hazard levels, noting that "Congress made no mention of economic or market factors in any of" the provisions governing the identification of lead-based paint hazards.[35] Nor did Congress mention costs or economic factors in CERCLA section 102(a).

Similar to the Clean Air Act, RCRA, and TSCA, CERCLA establishes separate processes for the designation of a hazardous substance (in which costs cannot be considered) and for decisions about how to remediate the substance (in which costs can be considered along with other relevant factors).[36] EPA's interpretation of CERCLA section 102(a) preserves that "identification versus implementation dichotomy"[37] and appropriately limits cost considerations to the development of remedial plans for a particular site, when EPA will also be able to assess the public health benefits associated with such remediation. Any consideration of costs to avoid the designation of hazardous substances would violate CERCLA's text and erase the distinction that Congress established between the criteria for hazardous substance designations and for remedy selection. We urge EPA to maintain its interpretation of section 102(a) in its final PFOA and PFOS rule and in any future hazardous substance designations.

C. EPA Should Lower the Reportable Quantity for PFOA and PFOS to Cover All Releases

When designating hazardous substances under CERCLA, EPA "shall" establish a "reportable quantity" ("RQ") above which releases of the substance must be reported to the National Response Center.[38] Upon receiving a report, "[t]he National Response Center shall convey the notification expeditiously to all appropriate Government agencies, including the Governor of any affected State," allowing those agencies to assess the threat posed by the release and take appropriate responsive action.[39] The National Response Center also publishes all reported release information online, informing impacted communities of their potential exposures to hazardous substances.

---

[32] *Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 448–49 (D.C. Cir. 2018) (quotation omitted).
[33] 15 U.S.C. § 2683.
[34] *Id*. § 2681(10).
[35] *A Cmty. Voice v. EPA*, 997 F.3d 983, 990–92 (9th Cir. 2021).
[36] *See id.* at 990 (explaining that TSCA "deals separately" with the identification of lead paint hazards and implementation of plans to abate those hazards).
[37] *Id.*
[38] 42 U.S.C. § 9602(a).
[39] *Id.* § 9603(a).

Congress gave EPA broad discretion to determine the appropriate RQ for each hazardous substance, while setting a default threshold of one pound per 24 hours that applies "[u]nless and until superseded by [EPA] regulations."[40] EPA has modified that RQ for many hazardous substances, increasing the default reporting level for some and establishing a wholly different scale for radionuclides because "releases of much less than one pound . . . may present a substantial threat to public health or welfare or the environment."[41] In its proposed PFOA and PFOS hazardous substance designations, EPA left the default RQ of one pound in place even though releases of far less than one pound of PFOA and PFOS also present a substantial threat to public health and the environment.[42]

EPA should lower the RQ and require reporting of all known PFOA and PFOS releases, which would slow the spread of PFAS contamination by enabling prompt remediation following an environmental release. EPA stated that "[o]nce EPA has collected more data on the size of releases and the resulting risks to human health and the environment, the Agency may consider issuing a regulation adjusting the reportable quantities for these substances."[43] But there is no need for additional data or a separate rulemaking process, since EPA already has the information required to establish a lower RQ for both PFOA and PFOS.

As EPA has acknowledged, multiple studies have found that PFOA and PFOS pose health risks below their respective limits of detection, meaning "*any detectable level* of PFOA or PFOS will result in" potential harm to children and others.[44] All environmental releases of PFOA and PFOS are thus of potential public health concern, and they should be promptly reported so regulatory officials can assess the threat and take action to contain or remediate the release before it spreads through surface water, groundwater, or other environmental pathways. In contrast, EPA's proposed RQ would allow companies to release massive amounts of PFAS-containing waste before triggering any CERCLA requirements. For a firefighting foam product containing one part-per-million of PFOA or PFOS, EPA's proposed RQ would permit the release of up to 1,000,000 pounds of the foam without any CERCLA reporting, equivalent to approximately 120,000 gallons of the concentrate that is used to create the foam or approximately 4,000,000 gallons of the foam after it is mixed with water for use.[45] If PFOA and

---

[40] *Id.* § 9602(b); 40 C.F.R. § 302.6(a).
[41] Proposed Rule, Administrative Reporting Exemptions for Certain Radionuclide Releases, 60 Fed. Reg. 40,042, 40,043 (Aug. 4, 1995) (codified at 40 C.F.R. § 302.4 app.B).
[42] 87 Fed. Reg. at 54,429 ("EPA is setting the RQ by operation of law at the statutory default of one pound pursuant to Section 102(b) of CERCLA.").
[43] 87 Fed. Reg. at 54,416.
[44] EPA, EPA/822/F-22/002, *Technical Fact Sheet: Drinking Water Health Advisories for Four PFAS (PFOA, PFOS, GenX Chemicals, and PFBS)* 5 (June 2022) (emphasis added), https://www.epa.gov/system/files/documents/2022-06/technical-factsheet-four-PFAS.pdf.
[45] Williams Fire & Hazard Control, *New York State Rule Regulating PFOS and PFOA: Implications for Tyco Fire Protection/Williams Customers* 2 (June 23, 2016), https://www.williamsfire.com/uploads/media/NYSDEC_Response_Williams_letterhead_-_06-

PFOS releases of that magnitude are not reported to the National Response Center, then by the time federal, state, and local officials learn of the releases (if at all), it will often be too late to contain the spread of the PFAS or to prevent exposures to nearby communities.

When dealing with persistent, bioaccumulative, and toxic chemicals like PFOA and PFOS, it is particularly important to immediately respond to any spills or releases, since the longer that PFOA and PFOS remain in the environment, the farther they spread and the harder it is to contain their harms. CERCLA authorizes EPA to adjust the default RQ in order to "focus [EPA's] resources on those releases that are more likely to pose potential threats to public health or welfare or the environment, while relieving the regulated community and government emergency response personnel from the burden of making and responding to reports of releases that are less likely to pose such threats."[46] All PFOA and PFOS releases "pose potential threats to public health or . . . the environment," including at levels far below one pound per day. EPA should set RQs that reflect those chemicals' serious risks.

D. EPA Should Expeditiously Designate Additional PFAS as CERCLA Hazardous Substances

In addition to promptly finalizing its proposal to designate PFOA and PFOS as hazardous substances under CERCLA, EPA should expeditiously designate additional PFAS based on existing authoritative assessments for individual chemicals within the class, EPA's recognition that PFOA and PFOS precursors degrade into these hazardous substances in the environment, and substantial evidence that the broader class of PFAS satisfies the statutory definition of hazardous substances.

The proposed rule states that "in 2022, the EPA will be developing an advance notice of proposed rulemaking seeking comments and data to assist in the development of potential future regulations" to designate additional PFAS compounds as hazardous substances under CERCLA.[47] EPA initially expected to begin that process in the spring of 2022, yet to date it has not sent any notice or advance notice of proposed rulemaking ("ANPRM") to the Office of Management Budget to review.[48] While we support EPA's pursuit of additional hazardous substance designations for PFAS, there is no need for EPA to publish an advance notice of proposed rulemaking before proposing to designate as hazardous those PFAS for which an EPA health advisory level, Agency for Toxic Substances and Disease Registry toxicological profile,

---

23-2016.pdf; Interstate Tech. Regul. Council, *Aqueous Film-Forming Foam* 5 (Oct. 2018), https://pfas-1.itrcweb.org/fact_sheets_page/pfas-fact-sheet-afff-10-3-18.pdf ("For legacy fluorotelomer AFFF, it would normally require a release of thousands of gallons of foam concentrate to result in release of 1 pound of PFOA.").

[46] EPA, EPA/540/R-94/005, *Questions and Answers on Release Notification Requirements and Reportable Quantity Adjustments* 36 (Jan. 1995), https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=600007A1.txt.

[47] 87 Fed. Reg. at 54,418.

[48] *See* PFAS Roadmap at 17 (2021).

EPA Integrated Research Information System assessment, or other authoritative assessment provides the requisite evidence that the chemical(s) "may present substantial danger to the public health or welfare or the environment" when released.[49] In these circumstances, publishing an ANPRM would unduly delay the CERCLA designation of substances that are already known to be hazardous. EPA can just as effectively, and more quickly, "engage robustly with communities near PFAS-contaminated sites to seek their input and learn about their lived experiences" by proceeding directly to a notice of proposed rulemaking.[50]

Likewise, EPA should expeditiously publish a proposed rule to list as hazardous substances all PFAS precursors that degrade to produce PFOA or PFOS. As EPA acknowledged in the proposed rule, in addition to direct environmental releases of PFOA and PFOS, these hazardous substances form in the environment "by chemical or biological degradation from a large group of related PFAS (i.e., precursor compounds)."[51] EPA correctly recognized that this phenomenon will contribute to continued "[e]nvironmental contamination and resulting human exposure to PFOA and PFOS . . . for the foreseeable future," despite steps to phase out intentional production of PFOA and PFOS.[52] And it is self-evident that PFOA and PFOS generated from environmental releases of precursor chemicals pose the same "substantial danger to the public health or welfare or the environment" that justifies the designation of PFOA and PFOS as hazardous substances.[53]

At the same time, EPA should pursue a class-based hazardous substance designation for a broader PFAS category. There is extensive precedent for adding chemical categories to the CERCLA hazardous substances list,[54] and there is an emerging consensus that PFAS should be evaluated and regulated on a class basis due to common toxicity, persistence, and mobility traits as well as evidence that PFAS precursors can transform into long- and short-chain PFAS in the

---

[49] 42 U.S.C. § 9602(a); *see*, *e.g.*, EPA, EPA/822/R-22/005, *Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Dimer Acid Ammonium Salt (CASRN 62037-80-3), Also Known as "GenX Chemicals"* (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-genx-2022.pdf; EPA, EPA/822/R-22/006, *Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)* (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-pfbs-2022.pdf; Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls* (May 2021), https://www.atsdr.cdc.gov/ToxProfiles/tp200.pdf.

[50] PFAS Roadmap at 17.

[51] 87 Fed. Reg. at 54,418.

[52] *Id.* at 54,417.

[53] 42 U.S.C. § 9602(a).

[54] *See* EPA, EPA/550/B-21/001, *List of Lists: Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-to-Know Act (EPCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and Section 112(r) of the Clean Air Act (CAA)* app.G (Apr. 2022) (CERCLA Hazardous Substances – Chemical Categories), https://www.epa.gov/system/files/documents/2022-04/list_of_lists_compiled_april-2022.pdf.

environment.[55] We urge EPA to move quickly to develop a proposed hazardous substance designation for a PFAS category, which is essential to fulfill the Administration's commitments to "[b]roaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems,"[56] "[m]aximize responsible party performance and funding for investigations and cleanup of PFAS contamination," and ensure equitable access to remediation resources in affected communities.[57]

Conclusion

Thousands of communities across the country are contaminated by PFAS, and countless others are threatened by releases that were never reported and have yet to be detected.[58] For decades, the costs of investigating and remediating that contamination have fallen largely on those communities and their local water providers, as opposed to the parties that created the hazard. The designation of PFOA and PFOS will start to change that, expanding the reporting of releases and shifting clean-up costs from the public to the parties responsible for PFAS contamination. EPA should finalize that rule with a lower RQ that captures all detectable PFOA and PFOS releases, immediately propose hazardous substance designations for other PFAS with existing toxicity assessments, and pursue a class-based hazardous substance designation for all PFAS.

If you have any questions about these comments, please contact Jonathan Kalmuss-Katz (jkalmusskatz@earthjustice.org) or Katherine O'Brien (kobrien@earthjustice.org).

Respectfully submitted,

Alabama Rivers Alliance
Alaska Community Action on Toxics
Alliance for the Great Lakes
Breast Cancer Prevention Partners
Cahaba River Society
Center for Environmental Health
Chesapeake Bay Foundation
Children's Environmental Health Network
Clean+Healthy
Clean Cape Fear
Delaware Riverkeeper Network

---

[55] *See, e.g.*, Zhanyun Wang et al., *A Never-Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)?*, 51 Env't. Sci. & Tech. 2508 (2017), https://doi.org/10.1021/acs.est.6b04806; Carol F. Kwiatkowski et al., *Scientific Basis for Managing PFAS as a Chemical Class*, 7 Env't Sci. & Tech. Letters 523 (2020), https://doi.org/10.1021/acs.estlett.0c00255.
[56] PFAS Roadmap at 5.
[57] *Id.* at 9.
[58] *See PFAS Contamination in the U.S.*, Env't Working Grp. (June 8, 2022), https://www.ewg.org/interactive-maps/pfas_contamination/.

Earthjustice
Ecology Center
Environmental Defense Fund
Food & Water Watch
Freshwater Future
GreenLatinos
Green Science Policy Institute
Harpeth Conservancy
Illinois Council of Trout Unlimited
League of Conservation Voters
Merrimack Citizens for Clean Water
Midwest Environmental Advocates
Missouri Confluence Waterkeeper
Moms for a Nontoxic New York
National PFAS Contamination Coalition
Natural Resources Defense Council
NC Conservation Network
Ohio Environmental Council
Oregon Environmental Council
PfoaProject NY
River Network
Sierra Club
Southern Environmental Law Center
Union of Concerned Scientists
U.S. PIRG Education Fund
Waterkeeper Alliance
Waterkeepers Chesapeake
Zero Waste Washington

National Waste & Recycling Association℠
Collect. Recycle. Innovate.

SWANA
SOLID WASTE ASSOCIATION OF NORTH AMERICA

November 7, 2022

Submitted electronically to: *https://www.regulations.gov*

Ms. Michelle Schutz
Office of Superfund Remediation and Technology Innovation (5202T)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OLEM-2019-0341; Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances

Dear Ms. Schutz:

The National Waste & Recycling Association (NWRA) and Solid Waste Association of North America (SWANA) are pleased to submit comments on the U.S. Environmental Protection Agency's (EPA's) proposal to designate perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). NWRA and SWANA represent companies, municipalities, and professionals in the solid waste industry. NWRA is a not-for-profit trade association representing private solid waste and recycling collection, processing, and management companies that operate in all fifty states. SWANA is a not-for-profit professional association in the solid waste management field with more than 10,000 members from both the private and public sectors across North America. Members of both organizations strive to deliver collection, composting, recycling, and disposal services that are protective of the environment in a safe, science-based, and technologically advanced manner.

NWRA and SWANA members are pleased that EPA has committed to numerous actions under the agency's PFAS Strategic Roadmap to safeguard public health, protect the environment, and hold accountable manufacturers and heavy users of these compounds. Our sector also supports EPA's focus on broadening and accelerating the cleanup of per- and polyfluoroalkyl substance (PFAS) contamination; nevertheless, we are concerned that designating PFOA and PFOS as CERCLA hazardous substances, without providing accompanying relief in recognition of the unique role served by the solid waste industry, would impede cleanup efforts and lead to substantial environmental cleanup liability, impose significant additional costs on essential public services and their customers, and have broad repercussions throughout the economy, without any measurable environmental benefit. We therefore request that EPA consider these comments in ensuring that the rulemaking adheres to the "polluter pays" principle of CERCLA.

I. Modern Landfills are Effective Solutions to Manage Wastes Containing PFAS.

Modern landfills are essential public services[1] that are subject to extensive and evolving federal, state, and local environmental, health, and safety requirements, including the Resource Conservation and Recovery Act (RCRA), the Clean Air Act, and the Clean Water Act. Regulations established under Subtitle D of RCRA establish minimum federal criteria for the operation of municipal solid waste, industrial waste, and special waste landfills, including design criteria, location restrictions, financial assurance, strict environmental monitoring, corrective action protocols (if triggered), and closure and post-closure periods to ensure facilities will not be a threat to human health and the environment. Similarly, Subtitle C of RCRA and its accompanying regulations govern the permanent disposal of hazardous wastes, and these facilities employ even greater environmental controls, which can include double liner systems, waste immobilization techniques, advanced leachate collection systems, extensive groundwater monitoring systems, offsite discharge mitigation protocols, leak detection systems, and enclosed and controlled offload areas. Both Subtitle C and Subtitle D landfills are highly regulated by permit(s) at the state level, as they typically are subjected to additional monitoring obligations as well as construction and operational requirements that go beyond the federal framework.

As a result of the stringent environmental controls required by federal and state regulation, and in recognition of our role as stewards of the environment, our industry has made significant investments to ensure that landfills are designed, constructed, and operated to reduce their environmental impact. For these reasons, EPA recognized in its *Interim Guidance on the Destruction and Disposal of PFAS and Materials Containing PFAS* that disposal of PFAS-contaminated wastes at hazardous or solid waste landfills can be effective options for managing PFAS by sequestering these compounds and preventing society from being re-exposed.[2]

II. The Proposed Rule would Replace CERCLA's "Polluter Pays" Principle with a "Community Pays" Model, Imposing Significant Costs on Landfill Customers and Ratepayers.

It is important for EPA to recognize that landfills neither manufacture nor use PFAS; instead, they are <u>passive receivers</u> of materials containing PFAS—compounds that are ubiquitous in residential and commercial waste streams—that must be managed once discarded. Research has shown that landfills effectively sequester a high percentage of PFAS compounds, especially longer-chain compounds such as PFOA and PFOS.[3] As rain percolates through landfills, the liquid will pick up some contaminants including a small amount of PFAS compounds not sequestered in the landfill environment. The resultant liquid is called leachate. Landfills are legally required to remove leachate from landfill collection systems and to properly manage this wastewater in order to protect groundwater resources. These management techniques can include onsite management, treatment prior to disposition or discharge, or collection and transport to wastewater treatment facilities. All of these activities are subject to regulatory permitting and oversight.

Despite the stringent management processes currently followed by our industry, a designation of PFOA and PFOS as CERCLA hazardous substances virtually guarantees that private parties—manufacturers of these compounds and other parties responsible for site contamination—will bring CERCLA claims for contribution

---

[1] *See Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID-19 Response*, V. 4.0, CYBER SECURITY & INFRASTRUCTURE SECURITY AGENCY (Aug. 18, 2020).

[2] *See Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances*, U.S. ENVT'L PROT. AGENCY (Dec. 18, 2020), *at* https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.

[3] *See, e.g., PFAS Waste Source Testing Report*, SANBORN, HEAD & ASSOCIATES, INC. (Oct. 2019), *at* https://anrweb.vt.gov/PubDocs/DEC/SolidWaste/OL510/OL510%202019.10.15%20NEWSVT%20PFAS%20Source%20Testing%20Rpt%20-%20Final.pdf.

against landfills and other essential public service providers such as water and wastewater utilities that are also passive receivers of PFAS. Given that CERCLA imposes joint, several, and retroactive environmental cleanup liability to parties connected with the presence of a hazardous substance at a site, designating PFOA and PFOS as hazardous substances will, at a minimum, generate significant litigation costs for lawful PFAS-containing waste disposal and discharges going back decades.

This type of inequitable outcome has occurred in previous CERCLA matters. As an example, industrial parties determined to be responsible under CERCLA for the cleanup of the Passaic River in New Jersey brought contribution actions against 261 third-party defendants—including 70 municipalities and other public entities—contending that they bore site cleanup responsibility. This action resulted in litigation spanning eight years and culminating in a payment of $35.4 million by these minor parties, many of whom were merely passive receivers of the contamination at issue.

Extensive litigation costs, as well as potential significant costs relating to PFAS remediation, would be passed along to communities, drinking water and wastewater treatment facilities, and the biosolids management sector—all of which rely on landfills for disposal of media containing PFAS. These cost increases, as well as similar cost increases passed through to drinking water and wastewater treatment ratepayers, likely would have a significant and disproportionate impact on low-income households that rely on the affordability of services that the waste sector and other passive receivers provide.

III. PFAS Treatment and Residuals Management Will Increase Costs to Communities but Will Not Reduce CERCLA Liability.

It has been suggested that the industry could simply treat leachate to eliminate any PFAS prior to discharging to wastewater treatment plants in order to reduce potential CERCLA liability presented by the proposed rulemaking. This premise is flawed for several reasons. Firstly, implementing treatment methods in the present day and into the future does not address potential liabilities for contribution actions that may be brought for cleanups stemming from prior POTW discharges.

Secondly, this premise does not recognize the current limitations of PFAS treatment technologies and their associated uncertainties and costs. Our industry is at the forefront of developing technologies for PFAS treatment and residuals management, however technologies for PFAS removal from leachate at scale are still developing and require a multi-step process that includes (1) pretreatment of leachate to address non-PFAS constituents, (2) subsequent PFAS treatment using one or more removal technologies (which creates PFAS-containing residuals), and (3) PFAS residuals treatment/management. Since most landfills rely on wastewater treatment plants for their leachate discharge, undertaking leachate pretreatment followed by PFAS treatment will add significantly to the costs of landfill operation.[4] The estimated capital cost to implement leachate pretreatment and PFAS treatment at a moderate-sized landfill (i.e., biological treatment of 30,000-40,000 gallons per day of leachate) to the extent necessary to minimize PFAS in leachate ranges from $2 million to $12 million, or potentially far more.[5] An additional layer of potential CERCLA liability could drive up these costs significantly and would ultimately be borne by the communities that rely on economical solid waste management services instead

[4] These costs will be driven, in part, by potential future regulation under the Safe Drinking Water Act, Clean Water Act, and other federal and state authorities.

[5] The standards that would govern a PFOA or PFOS cleanup action currently are unclear, complicated by a patchwork of state regulatory standards, unknown criteria that would be required for remedial actions, and EPA's interim drinking water health advisories for PFOA and PFOS. As such, the costs of PFAS treatment borne by landfills and their customers could far exceed these estimates.

of PFAS producers and manufacturers.

Moreover, since current technologies are unable to completely destroy PFAS, further management of residual PFAS waste streams—including biosolids and spent filters—is necessary to stabilize or otherwise limit their ability to reenter leachate. The costs and operational effectiveness for PFAS residuals management is less understood as most technologies have not been evaluated at full-scale. Based on general conversations with technology developers and estimates/extrapolations from small-scale studies, however, we anticipate that implementing new technologies for PFAS removal and subsequent residuals management could increase the costs of treating landfill leachate by approximately $0.06 to $0.39 (potentially even higher) per gallon of raw leachate processed (i.e., a cost increase of at least 400% to 800%). Increased costs associated with PFAS management thus could total approximately $966 million to $8.187 billion per year for municipal solid waste landfills alone. These costs typically cannot be absorbed by local governments with municipally operated landfills.

IV. The Mere Prospect of Designating PFOA and PFOS as CERCLA Hazardous Substances Already is Disrupting the Interdependence of Drinking Water and Wastewater Treatment Facilities, Biosolids Management, and Landfill Operations—and Could Have Much Broader Unintended Consequences on Administration Priorities.

Wastewater treatment facilities generate biosolids as a byproduct of their treatment activities. Similarly, drinking water treatment facilities generate spent filter materials from their operations. Expectedly, these biosolids and spent filter media may contain some amount of PFAS removed from the final treated wastewater and drinking water. Wastewater treatment facilities rely on landfills for biosolids management and drinking water treatment facilities depend on landfills for disposal of filter materials that may contain PFAS. At present, there are three viable options for management of biosolids: incineration, land application, and landfilling. At a time when incineration and land application are increasingly being prohibited, any further disruption to biosolids management could have a tremendous impact on municipal budgets and the environment.

Designating PFOA and PFOS as hazardous substances under CERCLA would impel landfill operators to revisit their waste acceptance criteria, likely choosing to limit inbound wastes with known elevated concentrations of PFAS—including filter materials, biosolids, and impacted soils—and/or increase disposal costs for certain media. Indeed, the mere prospect of a CERCLA designation has begun to disrupt the interdependence of the drinking water, wastewater, and solid waste sectors, as wastewater treatment facilities have begun to prohibit the acceptance of leachate while landfills are considering similar restrictions on the acceptance of biosolids and other PFAS-containing materials.

Regulation of PFOA and PFOS under CERCLA also could inadvertently undercut the Administration's broader environmental goals. The increased costs associated with disposal that are attributable to the rulemaking could incentivize bad actors to seek alternative means of disposal of PFAS-contaminated media and remediation wastes that are less protective of public health and the environment. Landfill operators choosing to limit specific inbound streams of waste containing elevated levels of PFAS also could curtail the ability of some wastewater treatment facilities to continue operating and frustrate EPA and DOD cleanup activities around military installations and other affected communities.

Moreover, EPA's action could lead to decreased composting services nationwide. Food waste compost may contain PFAS due to contact with PFAS-lined packaging materials. As a result, a CERCLA designation could result in communities diverting food waste from organics recycling programs, hindering federal, state, and local climate and waste reduction goals. Finally, and as mentioned above, the increased costs on ratepayers that are

attributable to the proposed rule likely will have disproportionate adverse impacts on low-income communities and frustrate the Administration's broader policies around environmental justice.

V. Recommendations

The solid waste sector and the communities we serve should not be held financially or legally liable under CERCLA for PFAS contamination, as landfills are only passive receivers of PFAS and are part of the long-term solution to manage these compounds. In its proposed designation, EPA announced that it "will use enforcement discretion and other approaches to ensure fairness for minor parties who may have been inadvertently impacted."[6] We greatly appreciate EPA's apparent willingness to exercise its discretion to foster equitable outcomes in direct enforcement matters; however, our industry remains concerned that this assurance would not sufficiently insulate landfills from third-party contribution litigation as discussed above. Accordingly, we suggest that concrete liability protections should be implemented in conjunction with this proposed rulemaking and respectfully request that EPA and the Interagency Policy Committee on PFAS[7] consider exercising existing legal authority to provide relief to landfills and other passive receivers of PFAS. *See, e.g.,* 42 U.S.C. §§ 9602(a) and 9615 (providing flexibility in the promulgation of regulations under CERCLA).

In the event EPA opines that it has limited authority to provide the solid waste sector with relief from third-party contribution litigation, the Administration should work with Congress to support a narrow legislative exemption from CERCLA liability in cases where a landfill discharges leachate in compliance with all applicable laws and regulations. Doing so would keep CERCLA liability on the industries that created and profited from these PFAS compounds —not on taxpayers.

Thank you for your consideration of our comments, and we look forward to continuing to partner with EPA to ensure the safe and effective management of waste streams containing PFAS. Should you have any questions about this letter, please contact Anne Germain, COO & SVP of Regulatory Affairs for NWRA, at agermain@wasterecycling.org. You may also contact Jesse Maxwell, Senior Manager, Advocacy & Safety for SWANA, at jmaxwell@swana.org.

Very truly yours,

Darrell K. Smith

Darrell K. Smith
President & CEO
National Waste & Recycling Association

David Biderman
Executive Director & CEO
Solid Waste Association of North America

[6] *EPA Proposes Designating Certain PFAS Chemicals as Hazardous Substances Under Superfund to Protect People's Health*, U.S. ENVT'L PROT. AGENCY (Aug. 26, 2022), *at* https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund.

[7] We request that the interagency committee broaden its scope when considering CERCLA liability concerns caused by the use of PFAS-containing firefighting foams at airports to include similar concerns from the waste sector. Just as certain airports are required by law to use firefighting foam containing PFAS, permitting authorities often require landfills to accept waste streams containing PFAS.

POWER!

Protecting Our Water,
Environment, and Ratepayers!

November 7, 2022

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Mr. Barry Breen
Acting Assistant Administrator
Office of Land and Emergency Management
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

RE: PROPOSED RULE TO DESIGNATE PERFLUOROOCTANOIC ACID (PFOA) AND PERFLUOROOCTANESULFONIC ACID (PFOS) AS CERCLA HAZARDOUS SUBSTANCES; DOCKET NO. EPA-HQ-OLEM-2091-0341

Dear Administrator Regan and Assistant Administrator Breen,

Protecting Our Water, Environment, and Ratepayers Coalition ("POWER!") appreciates the opportunity to provide comments on the Environmental Protection Agency ("EPA") proposed rule to designate Perfluorooctanoic Acid ("PFOA") and Perfluorooctanesulfonic Acid ("PFOS") as Hazardous Substances under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA").[1] POWER! is a coalition of water agencies, wastewater agencies, and municipalities who, together, are writing today to comment on a number of areas of the proposed rule.

POWER! is encouraged that EPA is taking steps to address per- and polyfluoroalkyl ("PFAS") in our environment. However, POWER! believes the current proposed rule is premature and will have unintended negative consequences for water agencies and the public we serve. If the proposed rule is finalized, it will, at a minimum, subject public water and wastewater agencies to the threat of years-long contribution actions from PFAS manufacturers and citizen suits, require millions in legal fees, and increase costs and water bills for households across the country. In

[1] Environmental Protection Agency, *Proposed Rule to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 87 Fed. Reg. 54415 (Sept. 6, 2022). (hereinafter "Proposed Rule").

addition to the comments set forth below, POWER! requests that EPA delay finalizing the proposed rule and reconsider designating PFOA and PFOS as hazardous substances under CERCLA until appropriate standards and technologies are in place. Proceeding without the appropriate standards and adequate technologies is arbitrary and capricious. Our request is based on the following:

(1) More time is needed for EPA and the regulated community to fully ascertain the consequences of the proposed action, and to allow for full and complete comments on the effect of the designation of PFOA and PFOS as hazardous substances under CERCLA.

(2) More time is needed to allow EPA to complete a full Regulatory Impact Analysis and provide an opportunity for public input on the analysis before designating PFOA and PFOS as hazardous substances under CERCLA.

(3) More time would allow development of standards and technologies for the cleanup, handling, and disposal and/or destruction of PFOA and PFOS, all of which currently are subject to significant uncertainties, but will be required for site cleanups following a designation as hazardous substances under CERCLA.

(4) More time would allow EPA and other Federal Agencies to make progress in phasing out the pipeline of harmful PFAS use in the United States. As long as EPA and other Federal Agencies continue to permit products with harmful PFAS to be imported, created, and used in the United States, public utilities will continue to be passive receivers of additional harmful PFAS substances within their systems. It is the responsibility of EPA and other Federal Agencies to cut off the introduction and use of harmful PFAS in the United States.

I. INTRODUCTION

The Proposed Rule would designate PFOA, PFOS, and their salts and structural isomers as hazardous substances under CERCLA.[2] PFOA and PFOS have been used in industry and consumer products in the United States from the 1940s. The primary U.S. manufacturers of PFOA and PFOS voluntarily phased out their domestic production in the early 2000's. EPA only recently began to regulate PFOA and PFOS use under the Toxic Substances Control Act ("TSCA"), and there are still instances where it is produced domestically and is brought into the country on treated products.

---

[2] *Id.* at 54417. Reference to PFOA and PFOS throughout these comments also includes their salts and structural isomers.

Today, PFOA and PFOS are found or used in many consumer products such as carpets, clothing, fabrics, cookware, and firefighting foam.[3] PFAS are known as "forever chemicals" due to their resistance to environmental decomposition and ability to build up within the human body, animals, and the environment.[4] Scientific studies have shown that exposure to some PFAS substances in the environment may be linked to harmful health effects in humans and animals.[5] However, these studies are being challenged in court and in scientific journals.[6]

POWER! believes it is important to move aggressively to stop the introduction of additional PFOA and PFOS into the environment, and to develop cleanup, handling, transportation, and disposal and/or destruction standards and technologies for PFOA and PFOS. Without standards and technologies in place, this proposed rule is likely to cause many unintended consequences and costs for water and wastewater agencies and the public we serve, as described below. Our specific comments on the proposed rule follow.

II. DETAILED COMMENTS

COMMENT 1 – REGULATORY FRAMEWORK – THE DIRECT EFFECTS OF THIS PROPOSED RULE GO BEYOND WHAT EPA HAS CONSIDERED.

EPA is proposing to designate PFAS and PFOA as hazardous substances pursuant to the Agency's authority under CERCLA section 102. Starting directly with CERCLA is a novel approach that no EPA Administrator has used since CERCLA was signed into law in 1980.[7] Instead, Administrators have designated substances as hazardous under the Clean Water Act ("CWA"), Clean Air Act ("CAA"), or Resource Conservation and Recovery Act ("RCRA"), which has meant that some other environmental standards were in place before EPA unleashed CERCLA's strict liability standards, citizen suits, and contribution suits for a substance.

---

[3] Proposed Rule at 54417.
[4] *See PFAS – the 'Forever Chemicals'*, CHEMTRUST, https://chemtrust.org/pfas/ (last visited: Sept. 18, 2022); *Our Current Understanding of the Human Health and Environmental Risks of PFAS*, U.S. ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas (last updated March 16, 2022).
[5] *See, e.g.*, Agency for Toxic Substances and Disease Registry, An Overview of the Science and Guidance for Clinicians on Per- and Polyfluoroalkyl Substances (PFAS) (Dec. 6, 2019), https://www.atsdr.cdc.gov/pfas/docs/clinical-guidance-12-20-2019.pdf (last visited: Sept. 24, 2022).
[6] *See American Chemistry Council v. EPA*, Docket No. 22-1177 (D.C. Cir. 2022); *See also* Katherine Alfred, Chad Seidel, and Amlan Ghosh, *Does regulating per- and polyfluoroalkyl substances represent a meaningful opportunity for health risk reduction?*, AWWA Water Science (Aug. 23 2021).
[7] Comprehensive Environmental Response, Compensation, and Liability Act, Pub. L. 96-510; *See also* Proposed Rule at 54421.

Moreover, EPA has not fully described or apparently considered the impacts of the proposed designation. The proposed rule, and any proposed rule under §102(a) will have two categories of direct and automatic consequences:

(1) Reporting requirements, when a known release of the reportable quantity of the hazardous substance occurs; and

(2) The financial and liability responsibilities and concerns that result directly from the designation of a substance as a hazardous substance under CERCLA.

EPA has not acknowledged that designating PFOA and PFOS as hazardous substances under CERCLA will have any direct impacts other than basic reporting requirements. This is not correct. If finalized, the proposed designation *would* create potential liability for public utilities, and at the very least, cause years and millions of dollars of litigation and legal costs for publicly owned treatment works ("POTW"), water supply agencies and stormwater management agencies. CERCLA was designed to create liability for cleanup, an approach that is well described in the Congressional record and has played out over the decades since the law was enacted.[8] This liability, and the inevitable contribution suits from manufacturers under Section 113, have the potential to impose massive costs on POWER!'s members and similarly situated public agencies, despite the fact that water and wastewater agencies did not produce or intentionally use the PFOS and PFOA. This strict cleanup liability is the heart of the CERCLA statute. Whether EPA wants to label these central and inevitable statutory impacts and costs as direct or indirect, EPA has not fully considered or even acknowledged them – either for public agencies or the ratepayers and taxpayers they serve.

The Direct Effect of Proposed Rule is the Full Power of CERCLA

In the Proposed Rule, EPA identified only three direct impacts: (1) Reporting and Notification Requirements for CERCLA Hazardous Substances; (2) Requirements Upon Transfer of Government Property; and (3) Requirements for DOT to List and Regulate CERCLA Hazardous

---

[8] Specifically, the Congressional record on the development of CERCLA states the direct impact of CERCLA is "to initiate and establish a comprehensive response and financing mechanism to abate and control the vast problem" of pollution. (CERCLA-LH 3-A, 1980 WL 356046 (A.&P.L.H.), 6.) At a field hearing held by the Senate Committee on Environment and Public Works in 1979, Senator Daniel Patrick Moynihan stated in his opening remarks that CERCLA would "provide immediate assistance in responding to emergency situations caused by releases of hazardous wastes; to compensate people injured by hazardous waste contamination; and to support state programs for the identification and treatment of abandoned hazardous waste sites. (CERCLA-LH 20-B, 1979 WL 211365 (A.&P.L.H.), 3.)

Substances.[9] These three consequences, while direct impacts, do not convey the full list of direct impacts of this proposed rule.

EPA has not considered the full range of implications that will flow from the proposed rule. The legislation establishes a multi-step process that would ultimately allow for cleanup of a polluted site. This includes designating an area a "hazardous site," or "Superfund site;" engaging in a site assessment and cleanup; and providing EPA, citizen groups, and other potentially responsible parties ("PRPs") the opportunity to pursue cleanup costs and recover costs from additional PRPs. Thus, the designation of a hazardous substance is just the first step in the entire CERCLA Process. Once designated, the entire force of CERCLA is available to be pursued.

The direct effect of the proposed rule will be to not only require reporting of a known release of the reporting requirement of a hazardous substance, but will also create the ability for Superfund sites to be designated solely on the basis of PFOA or PFOS contamination, and will open up PRPs to liability – even if they are a passive receiver as the members of POWER! are – and can leave POWER! members solely responsible for the cleanup and environmental mitigation. The direct impact will also require the development and installation of new or modified equipment and testing procedures – which as described below, are mostly unavailable at this time.

<u>POWER! respectfully requests that EPA review and consider all direct and foreseeable indirect impacts of the proposed designation to ensure unintended consequences are properly addressed before they occur.</u>

COMMENT 2 – EPA SHOULD USE OTHER REGULATORY AUTHORITIES TO ADDRESS PFOA AND PFOS BEFORE PROCEEDING UNDER CERCLA.

Without question, EPA's goal of addressing the risks of PFOA and PFOS in the environment is important. However, there have been other substances and chemicals that EPA has indicated posed a risk to human and environmental health and sought to address their presence through a variety of mechanisms including the CAA, CWA, RCRA, and the Safe Drinking Water Act ("SDWA").[10] Further, EPA and other Federal Agencies have taken steps to address the risks these other substances and chemicals pose by limiting or halting their production or use in the United States.

[9] Proposed Rule at 54429.

[10] *See* 46 U.S.C. § 101(14) (defining "hazardous substance" to include designation under 33 U.S.C. § 311(b)(2)(A)(Federal Water Pollution Control Act), 42 U.S.C. § 6921 (Solid Waste Disposal Act), 33 U.S.C. § 1317(a) (Federal Water Pollution Control Act), 42 U.S.C. § 7412 (Clean Air Act), 15 U.S.C. § 2606).

EPA's decision to use CERCLA as the first tool for addressing PFOA and PFOS is premature and leaves POWER! and other members of the public as targets for cleanup liabilities without clear standards or technologies. Generally, CERCLA site cleanup standards and responsibilities are informed by other statutes' regulatory frameworks to ensure consistency and full compliance across statutes. For example, arsenic is regulated by the EPA under a wide range of statutes – CAA, CWA, SDWA, RCRA, and CERCLA.[11] Each statute provides different components for handling, dealing, and disposing of this hazardous substance. Further, each establishes the parameters required for CERCLA to be implemented effectively. Neither PFOA nor PFOS have an existing regulatory framework that facilitate effect implementation of CERCLA.

In Fall 2021, EPA announced an updated plan to strategically tackle the growing concerns regarding PFAS.[12] This multi-year plan sets forth the agency's proposal to address PFAS through a three-pronged approach of: research, restrict, and remediate. This multi-pronged approach allows EPA to review the evolving research on the impacts of PFAS and determine the best actions required to prevent further harms to human and environmental health. EPA is currently reviewing PFOA and PFOS under CWA, SDWA, and RCRA, however these regulatory measures are not currently open for review or comment by the public.[13] The PFAS Roadmap also sets forth EPA's goal to see PFAS designated under CERCLA. However, CERCLA designation needs to be the penultimate regulatory action, not the first. Further, the PFAS Roadmap discusses the restriction of the manufacturing and use of products with PFAS among society, until these actions are taken, PFAS, including PFOA and PFOS, will remain present in society. No regulation under CAA, CWA, SDWA, RCRA, TSCA, or even CERCLA will not cut off the presence within the Untied States. PFAS will only stop being present in the United States when EPA and other Federal Agencies take the necessary steps to stop the introduction of PFAS in our society through products and manufacturing.[14]

---

[11] LU-IN, *Arsenic policy and guidance* (last update Jun. 17, 2022) (https://clu-in.org/contaminantfocus/default.focus/sec/arsenic/cat/policy_and_guidance/)

[12] *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024,* U.S. ENVIRONMENTAL PROTECTION AGENCY (OCT. 18, 2021), https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf (hereinafter "PFAS Roadmap").

[13] EPA, *Memo - Addressing PFAS Discharges in EPA-Issued NPDES Permits and Expectations Where EPA is the Pretreatment Control Authority* (Apr. 28, 2022) (https://www.epa.gov/system/files/documents/2022-04/npdes_pfas-memo.pdf); OIRA, *Pending EO 12866 Regulatory Review* (Oct. 6, 2022) (https://www.reginfo.gov/public/do/eoDetails?rrid=270912); EPA, *EPA Responds to New Mexico Governor and Acts to Address PFAS Under Hazardous Waste Law* (Oct. 26, 2021) (https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law).

[14] While the production of products with PFOA and PFOS is restricted to limited critical uses, products with PFOA and PFOS are still imported into the country and then used throughout society and migrate into the POTWs.

EPA is asking for public comment on a proposed rule without even a remote understanding, much less a complete analysis, of its effects. EPA acknowledges "numerous, significant uncertainties"[15] regarding key facts, such as the extent and type of contamination, and does not even provide an order-of-magnitude range of cleanup levels that may be required – clear signs that proceeding with regulation under CERCLA is premature.

EPA should use other regulatory authorities to address PFOA and PFOS contamination and existence and use in the United States, before proceeding under CERCLA. In order to fully analyze and comment on the impacts of the designation of PFOA and PFOS as hazardous substances under CERCLA, and what cleanup, handling, and disposal and/or destruction will entail, it is critical for standards to be in place under other statutes such as CAA, CWA, SDWA, and RCRA.

COMMENT 3 – DESIGNATING PFOA AND PFOS AS CERCLA HAZARDOUS SUBSTANCES AT THIS TIME IS PREMATURE AS IT IS UNCLEAR WHAT STANDARD WILL APPLY TO CLEANUP AND EPA'S HEALTH ADVISORY LIMITS ARE AT THIS POINT, IMPOSSIBLY LOW.

EPA should develop technological and regulatory standards for the disposal and/or destruction of PFOA and PFOS **before** the designation as hazardous under CERCLA. EPA should also provide, for public comment, information regarding what "cleanup" will mean and the range of standards that may be set for sites with PFOA/PFOS contamination.

EPA has historically relied on health advisory limits when setting cleanup standards for CERCLA sites. In June 2022, EPA published updated health advisories for PFOA and PFOS, EPA recommended levels of 0.004 parts per trillion (ppt) for PFOA and 0.02 ppt for PFOS. EPA acknowledged in its release that these levels are "below EPA's ability to detect at this time."[16] EPA is setting the stage for cleanups that are expected to reduce contamination significantly below levels that current technology can detect. To add to the uncertainty, as of the date this comment was submitted, the health advisories are being challenged in court for being "impossibly low."[17] Before finalizing the proposed designation, EPA should allow the courts to

[15] Proposed Rule at 54423. The proposed rule states that "decisions about cleanup and response are difficult to quantify due to numerous, significant uncertainties such as: (1) How many sites have PFOA or PFOs contamination at a level that warrants a cleanup actions; (2) the extent and type of PFOA and PFOS contamination at/near sites; (3) the extent and type of other contamination at/near sites; (4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and (5) the cleanup level required for these substances.
[16] Environmental Protection Agency, *Lifetime Drinking Water Health Advisories for Four Perfluoroalkyl Substances*, 87 Fed. Reg. 36848 (June 21, 2022).
[17] *American Chemistry Council v. EPA*, Docket No. 22-1177 (D.C. Cir. 2022).

provide certainty regarding the health advisory limits, and explain and take comment on how it plans derive cleanup standards in light of current and future technological limitations.

Unlike other hazardous substances such as arsenic, treatment and disposal technologies for PFOA and PFOS are still being developed and costs vary significantly based on geographic location.[18] POWER! members provide critical public health services, by providing clean drinking water and wastewater. Each responsibly manages the residuals of wastewater ("biosolids") that are naturally produced as a result of the wastewater treatment process. The designation of PFOA and PFOS as hazardous substance under CERCLA would create a significant impact on the management and disposal of biosolids – the use as land application, of landfills, sewage sludge incinerators ("SSI"), and other management of biosolids all pose their own risks and concerns as it relates to CERCLA's application of cleanups and liability. Biosolids are generated 24 hours a day, every day of the year, by every person in the United States, there is no possible way to halt the flow or production of these biosolids. It is imperative that the science and technology for handling, cleanup, and disposal be developed and implemented prior to a CERCLA designation of PFOA and PFOS.

EPA has acknowledged that there are currently technological deficiencies and uncertainties regarding the destruction of PFAS.[19] Designating PFOA and PFOS as hazardous substances under CERCLA before reliable methods of destruction exist is a recipe for confusion and litigation. The science and conclusive methods on destruction and/or disposal are not yet settled and EPA has acknowledged that time is needed to bridge this gap.[20]

<u>As many actions under CERCLA are informed by regulatory frameworks, science, and technology, EPA should delay finalizing the proposed designation and allow the time necessary for science to develop and inform standards for the disposal and destruction of PFOA and PFOS before a designation under CERCLA. EPA should also provide, for public comment, information on likely expectations for cleanup for PFOA and PFOS remediation sites.</u>

---

[18] EPA, *Economic Assessment (EA) of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances* (Aug. 2022) (https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0035); *See e.g.* EPA, *The Arsenic Rule Waste Disposal Options* (2015) (https://www.epa.gov/sites/default/files/2015-09/documents/disposal_options_janet_cherry.pdf).
[19] EPA*, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* at 7 (Dec. 18, 2020) (https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf).
[20] EPA*, Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* at 91 (Dec. 18, 2020) (https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf).

COMMENT 4 – EPA IS REQUIRED TO PRODUCE A REGULATORY IMPACT ANALYSIS FOR THE PROPOSED RULE.

EPA is required to produce a Regulatory Impact Analysis ("RIA") and release the RIA for public review and comment before taking any further action on the proposed rule.

Executive Order 12866 ("EO 12866") requires that an agency provide a Regulatory Impact Analysis ("RIA") for all significant regulatory actions the agency takes. EO 12866 defines a "significant regulatory action" as one that may have "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities" or "raise novel legal or policy issues."[21]

EO 12866 requires that an agency provide an RIA that includes "but is not limited to, the direct cost both to the government administering the regulation and to businesses and others in complying with the regulation and any adverse effects on the efficient functioning of the economy" and private markets, including the natural environment.[22] The Government Accountability Office has in turn defined direct costs of a government regulation to include the direct compliance costs such as additional paperwork, development and installation of new or modified equipment, and testing procedures.[23]

The lack of an RIA to support the proposed rule highlights the overall lack of certainty regarding the likely impacts of EPA's proposed action. Moving forward with the proposed rule under these circumstances would violate existing Administration policy. In Circular A-4, the Office of Management and Budget ("OMB") states that when proposing a federal regulation, a federal agency must "do more than demonstrate the possible existence of incomplete or asymmetric information."[24] Further, when an agency proceeds with a rulemaking, despite uncertainty having a significant effect on the cost analysis, the agency should explain what the harm from delay

---

[21] Exec. Order No. 12866 §3(f), 58 Fed. Reg. 51735 (Sept. 30, 1993).
[22] *Id.* §6(a)(3).
[23] Costs and Benefits of Government Regulation – Hearing before the Committee on Judiciary, CONGRESS (1978) (Testimony of Harry S. Havens, Director, Program Analysis Division, U.S. General Accounting Office) (Available at: https://www.gao.gov/assets/107970.pdf).
[24] OMB, *Circular A-4* at 5 (Sept. 17, 2003) (https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf).

would be.[25] When "uncertainty is due to a lack of data," it is recommended the federal agency defer the rulemaking.[26]

Comment 5 – Without More Information and Analysis of its Likely Impacts, EPA's Proposed Interpretation of § 102(a) of CERCLA is Arbitrary and Capricious

In the Proposed Rule, EPA interprets § 102(a) of CERCLA as "precluding the Agency from taking cost into account in designating hazardous substances."[27] EPA goes further and asserts that it is not required to conduct a cost analysis for the proposed rule.[28] There is a difference between taking the position that cost should not preclude a designation and deciding that the agency should act without fully considering or providing the public information on the likely impacts of its actions. Taking such a significant action without fully considering its impacts is arbitrary. This proposed rule is not merely definitional. It is a designation that invokes a broad and forceful environmental regulatory scheme and provides private and state rights of action that will have broad impacts on public water and wastewater agencies and their ratepayers across the country.

EPA has acknowledged that a designation under § 102(a) is for substances that "may present substantial danger to the public health or welfare or the environment."[29] EPA's recognition that PFOA and PFOS "may present substantial danger to the public health or welfare or the environment," is an acknowledgement by the agency of the applicability of OMB's directive that a cost analysis be done for all proposed rules where the primary benefit is improved public health and safety.[30] Therefore, to be in line with required analysis from OMB Circular A-4 and the Government Accountability Office, EPA must perform an analysis of, but not limited to, <u>why</u> it is hazardous, <u>how</u> it is hazardous, and <u>how</u> the hazardous substance will be dealt with including the likely standards and costs of the testing, equipment, and cleanup required to properly address the substance. Instead, EPA proactively described why it would <u>not</u> be complying with the requirements. This lack of analysis, and therefore lack of a complete record for public review and comment, is arbitrary and capricious as defined by the Administrative Procedures Act.[31]

---

[25] OMB, *Circular A-4* at 39 (Sept. 17, 2003) (https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf).
[26] OMB, *Circular A-4* at 39 (Sept. 17, 2003) (https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf).
[27] Proposed Rule at 54421.
[28] Proposed Rule at 54421.
[29] Proposed Rule at 54421.
[30] OMB, *Circular A-4* at 5 (Sept. 17, 2003) (https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf).
[31] 5 U.S.C. § 706(2)(A) (1966) (stating a Court shall "hold unlawful and set aside agency action, findings, and conclusion to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

POWER! believes a common sense reading of CERCLA and federal rules on promulgating regulations a full understanding and analysis of likely impacts when designating a hazardous substance. Before proceeding further, EPA should produce a Regulatory Impact Analysis ("RIA") and release it for public review and comment.

COMMENT 6 – EXISTING CASE LAW REQUIRES COST TO BE CONSIDERED WHEN PROMULGATING THIS RULE.

When designation of a pollutant is economically significant, EPA is required to consider cost. POWER! therefore requests EPA pause this rulemaking and conduct a full analysis of the economic impacts of the proposed designation.

As described above, Executive Order 12866 requires federal agencies to conduct an analysis of costs when a regulatory action is deemed significant.[32] EPA chose not to conduct this analysis and has attempted to support the decision with reference to existing case law.[33] Those efforts are misplaced. Existing case law, specifically the Supreme Court's decision in *Michigan v. EPA*, requires the Agency to consider costs when taking actions like those considered in the proposed rule.

The issue before the Court in *Michigan* was whether or not EPA had to consider costs when setting standards for regulation of hazardous air pollutants ("HAPs"). The Court concluded EPA "interpreted [the statute] unreasonably when it deemed cost irrelevant to the decision to regulate power plants."[34] The relevant section of the provision at hand in *Michigan* reads: "The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary after considering the results of the study required by this paragraph."[35] In *Michigan*, the Court found, even when applying *Chevron* deference,[36] the phrase "appropriate and necessary" encompasses the consideration of cost because it is unreasonable to impose billions of dollars in economic costs without an analysis and consideration of the costs imposed.[37]

---

[32] Exec. Order No. 12866, 58 Fed. Reg. 51735 (Sept. 30, 1993). Despite the designation as economically significant, EPA proceeded with proposing this rule without a RIA. (Office of Information and Regulatory Affairs, *OIRA Conclusion of EO 12866 Regulatory Review* (Aug. 8, 2022) (https://www.reginfo.gov/public/do/eoDetails?rrid=218011).)

[33] Proposed Rule at 54421.

[34] *Michigan v. EPA*, 576 U.S. 743 (2015).

[35] 42 U.S.C. § 7412(n)(1)(A).

[36] Under the *Chevron* doctrine, a Court grants deference to a federal agency's interpretation when: (1) the federal agency administers the statute at question; (2) Congress has given authority for the agency to act on the matter in question; and (3) the agency's interpretation is based on a permissible construction of the statute. *See Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843-45 (1984).

[37] *Michigan v. EPA*, 576 U.S. at 743.

The same language is at issue here. The relevant provision of CERCLA in the proposed rule here reads: "The Administrator shall promulgate and revise as may be appropriate, regulations designating as hazardous substances . . . when released into the environment may present substantial danger to the public health or welfare or the environment . . . ."[38] EPA has been given this authority within the larger context of CERCLA to ensure damages to the environment and risks to public health are cleaned up by the responsible parties. As with the provision in *Michigan*, § 102(a) requires EPA to consider a designation when appropriate to address the public and environmental welfare. Further, as with the Court's analysis in *Michigan*, CERCLA requires consideration of cost, in fact the word cost is stated at least 50 times throughout the statute.[39]

Given the stark contrast between EPA's analysis and Supreme Court case law, EPA should pause this rulemaking, do a full cost analysis of this economically significant proposed rule and reintroduce for complete consideration and comment by the public.

COMMENT 7 – CERCLA ALLOWS PRIVATE PARTIES AND STATES TO FORCE AND ENFORCE CLEANUP RESPONSIBILITY WITHOUT ACTION ON THE SAME BY EPA.

The impact of the proposed rule cannot be siloed from the entirety of CERCLA. It is therefore imperative for EPA to pause this rulemaking to consider the question of the likely impacts of state actions, citizen suits, and contribution actions on water agencies, wastewater agencies, municipalities, and their ratepayers.

In the proposed rule, EPA states that "designation alone does not require the EPA to take response actions, does not require any response action by a private party, and does not determine liability for hazardous substance release response costs."[40] EPA's comments do not take into consideration why a hazardous substance is designated under CERCLA in the first place.

Designation of a substance as hazardous under CERCLA primarily occurs to allow EPA, State Environmental Agencies, and citizen groups to hold polluters accountable by forcing cleanups of sites deemed contaminated by one or more hazardous substances. If the designation of a hazardous substance under CERCLA were only to permit site designation and reporting, then it would have been made clear in the statute that polluter responsibility for cleanups was not associated with the designation of a hazardous substance.

[38] 46 U.S.C. § 9602(a).
[39] 46 U.S.C. §§ 9601-9628. Two specific instances are: §101(24) in which the definition of "remedy" or "remedial action" includes the cost-effective consideration, as well as §121 in which CERCLA directs consideration of cleanup standards that are cost effective. (46 U.S.C. § 9601(24); 46 U.S.C. § 9621(G).)
[40] Proposed Rule at 54423.

EPA's own website contradicts the position taken by EPA in the proposed rule.[41] The website states that Citizen Enforcement is permitted under § 310(d) of CERCLA,[42] and states they are warranted when there is an "alleged violation of any [CERCLA] standard, regulation, condition, requirement, or order . . . ."[43] CERCLA permits a Court to award attorney fees, expert witness fees, as well as award other costs of litigation.[44]

EPA's current guidance on next steps regarding CERCLA enforcement of PFOA and PFOS is subjective and leaves POWER! members in a state of uncertainty. EPA stated that it does not have the authority to address the liability concerns raised with the designation of PFOA and PFOS.[45] However, that is not the case. EPA is not required to move forward with the proposed rule. As noted above, there are other statutory schemes that may provide a more appropriate vehicle for taking the initial steps to address PFOA and PFOS, and that can provide more certainty when proceeding under CERCLA.

Instead of taking that approach, EPA has stated that it will: (1) create new policy documents such as enforcement discretion policy and entry into settlement agreements; (2) analyze resolution on a site-specific basis; and (3) utilize equitable considerations.[46] EPA's proposal does not provide sufficient protection for POWER!'s members for the following two reasons.

First, the use of an enforcement discretion policy is inconsistent – its reliance, direction, and implementation can change region to region, with a change in personnel, and/or a change in administration. This policy would not adequately protect nor provide direction for the passive receivers who encounter PFOA and PFOS in the course of their diligent permitted work for the communities. Entry into settlement agreements, by the simple nature of the type of agreement, does not address or protect the entities that are doing what they are legally required to do by the standards and permits set forth for water agencies, wastewater agencies, and municipalities.

---

[41] EPA, *Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Federal Facilities* (https://www.epa.gov/enforcement/comprehensive-environmental-response-compensation-and-liability-act-cercla-and-federal).
[42] [42] EPA, *Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Federal Facilities* (https://www.epa.gov/enforcement/comprehensive-environmental-response-compensation-and-liability-act-cercla-and-federal).
[43] 42 U.S.C. § 9659(a)(1).
[44] 42 U.S.C. § 9659(c).
[45] EPA, *Overview Presentation: NPRM Designation of PFOA and PFOS as CERCLA Hazardous Substances* (Aug. 2022) (https://www.epa.gov/system/files/documents/2022-09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf).
[46] EPA, *Overview Presentation: NPRM Designation of PFOA and PFOS as CERCLA Hazardous Substances* (Aug. 2022) (https://www.epa.gov/system/files/documents/2022-09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf).

Second, it is important for EPA to recognize and implement a policy that will ensure those that passive receivers are not bearing the burden for polluters and to recognize the federal government's role in permitting the importation and use of PFOA and PFOS in society. Although the EPA attempts to do this by using equitable considerations when devising remediation plans, this is insufficient because it does not protect passive receivers in citizen suits where the EPA is uninvolved.

<u>In order to ensure POWER! members are not subjected to inconsistent or arbitrary implementation and enforcement, it is essential for EPA to provide a direct plan of enforcement, including the full regulatory framework discussed above so POWER! members may adequately plan and be on notice.</u>

COMMENT 8 – THE STATUTORY DEFINITIONS OF POTENTIALLY RESPONSIBLE PARTIES AND CURRENT EXEMPTIONS DO NOT PROTECT POWER! MEMBERS.

<u>POWER! requests EPA pause this rulemaking to ensure that the nation's water agencies, wastewater agencies, and municipalities are not subject to unwarranted litigation and potential liability – the costs of which will ultimately land with ratepayers.</u>

CERCLA's definitions of PRPs and the exemptions do not provide adequate protection for POWER!'s members. Before finalizing this proposed rule, EPA has a responsibility to consider significant effects it will have on water agencies, wastewater agencies, and municipalities.

CERCLA permits enforcement retroactively, joint and several liability, and negligence is not required for a party to be deemed responsible.[47] POWER! members are engaged in activities that do not intentionally create or use PFOA or PFOS substances. Because of the broad definition of PRPs under CERCLA, even this tangential relationship to the chemicals may be enough to trigger actions by states or private parties to attempt to bring them under the purview of the Act.

CERCLA defines PRPs as: (1) current owners or operators of a facility; (2) former owners or operators of a facility; (3) those who arrange for the disposal or treatment of hazardous substances; and (4) any person who accepts hazardous substances for transport of a hazardous substance.[48] POWER! members own, operate, and manage municipal stormwater systems; treat and distribute water in accordance with stringent standards and permits set forth by CWA and SDWA; collect, treat, and discharge wastewater in accordance with National Pollutant Discharge

[47] 42 U.S.C. § 9607.
[48] 42 U.S.C. § 9607.

Elimination System ("NPDES") permits; and responsibly manage the biosolids that are naturally produced as a result of the wastewater treatment process. POWER! members are all passive receivers of PFAS (including PFOA and PFOS). POWER! members do not intentionally create or add PFAS into their treatment systems. Members carry out these actions with the goal of protecting public health, enhancing water quality and sustainability, and protecting environmental health.

Congress recognized the inherent passive receipt of hazardous substances by water agencies, wastewater agencies, and municipalities when providing statutory exemptions from liability for "federally permitted releases."[49] As defined in the statute, "federally permitted discharges" includes those done in compliance with an NPDES permit, RCRA, SDWA, CAA, or CWA.[50] However, not all activities that involve water require a federal permit, and thus POWER!'s members remain exposed. Further, no matter the technology and treatment (once available) that POTWs may undertake to address PFOA and PFOS, PFOA and PFOS will continue to be present in society so long as EPA and other Federal Agencies permit its manufacturing, importation, and use in the United States.

Moreover, this exclusion only applies when limits for hazardous substances are set in a permit or statutory obligation. EPA has not yet set drinking water standards, treatment standards, nor do NPDES permits nationwide yet include limits or requirements for reduction of PFOA or PFOS. Even when EPA sets these standards, CERCLA's retroactive application can implicate water agencies, wastewater agencies, and municipalities.

<u>EPA's inaction on PFOA and PFOS through other regulatory schemes has left POWER! members vulnerable to the far-reaching arms of CERCLA. POWER! members request EPA pause this rulemaking and provide the certainty and protections it can through implementation of other regulatory PFOA and PFOS measures.</u>

[49] 42 U.S.C. § 9607(j).
[50] 42 U.S.C. § 9601(10).

COMMENT 9 – THE PROPOSED RULE CHANGES THE CERCLA PRINCIPLES OF "POLLUTER PAYS" TO "RATEPAYERS PAY"

CERCLA was created to ensure polluters were responsible and paid for the cleanup of their contamination of the environment and their risk to public health; however, in the context of water and wastewater utilities, EPA's actions are potentially shifting that burden to water and wastewater ratepayers. EPA's action will likely impose costs on individuals and communities that are least able to bear an increased cost for basic services, and will therefore inhibit the Agency's stated goal of advancing environmental justice.

EPA's proposed rule states that it wants to ensure taxpayers do not carry the brunt of the costs for polluters. Specifically, the proposed rule states "EPA and delegated agencies could recover PFOA and PFOS cleanup costs from potentially responsible parties, to facilitate having polluters and other potentially responsible parties, rather than taxpayers, pay for these cleanups."[51] EPA also states that this proposed rule would "allow costs to be shifted from the taxpayer to parties responsible for pollution under CERCLA."[52]

While the EPA's understanding would be the case if manufacturing and industry were the only parties threatened with being designated as PRPs, it fails to consider the real possibility of local government being designated as a PRP. The budgets of municipalities are based on the makeup of their taxpayer-base including instances where municipalities provide water and wastewater services to their constituencies. Additionally, public water districts and wastewater districts across the country are created by state law as a specialized form of local government. The budgets for these agencies are dependent on their ratepayer base – the same people EPA identifies as taxpayers. Therefore, the possible designation of local governments as PRPs will have the very impact that the EPA seeks to avoid under CERCLA.

Given the services POWER! members provide to their communities, PFAS enters their systems without their say. POWER! members perform their responsibilities to protect human and environmental health and duties directed by state and federal law to ensure the water and wastewater they are providing is at or above permitted requirements. As discussed above, the definition of PRP under CERCLA, the potential for citizen's suits and contribution actions, and the lack of protections provided by EPA expose POWER! members to significant litigation and potential cleanup costs. The funds for this litigation and cleanup would have to come from the ratepayers – placing a huge financial burden on the very people EPA said should not have to carry it.

[51] Proposed Rule at 54418.
[52] Propose Rule at 54422.

By not addressing the full regulatory scheme and having no mechanisms in place to provide protections for these public entities, EPA is not only directly imposing a financial liability on ratepayers across the country, but it is also providing polluters a potential pass on paying their full share for cleanups.

<u>By not implementing a full regulatory scheme and ensuring that water agencies, wastewater agencies, and municipalities are protected from liability for simply providing essential public services, EPA is contradicting its goal of protecting taxpayers. EPA's action will invite litigation attempting to shift those costs to ratepayers. The resulting costs will inhibit efforts to advance environmental justice.</u>

III. CONCLUSION

POWER! believes it is important for EPA to address the risks of PFAS, including PFOA and PFOS, in the environment. However, POWER! believes that EPA's proposed rule is premature because it precedes any attempt to understand the full impacts of a designation under CERCLA and precedes technologies or standards for cleanup, handling, or destruction and/or disposal of PFOA and PFOS.

POWER! reiterates the following requests for EPA to pause this rulemaking:

(1) POWER! requests that EPA review and consider all direct and foreseeable indirect impacts of the proposed designation to ensure unintended consequences are properly addressed before they occur.
(2) POWER! requests EPA to address PFOA and PFOS contamination under other regulatory authorities prior to proceeding under CERCLA.
(3) POWER! requests EPA allow the time needed to develop technology and standards for the disposal and/or destruction of PFOA and PFOS before the designation as hazardous under CERCLA. EPA should also provide, for public comment, information regarding what "cleanup" will mean and the range of standards that may be set for sites with PFOA/PFOS contamination.
(4) POWER! requests EPA produce and release the RIA for public review and comment before taking any further action on the proposed rule.
(5) POWER! requests EPA release a full analysis of the likely impacts of the proposed actions under § 102(a), otherwise, without this information, the action by EPA is arbitrary and capricious.
(6) POWER! requests EPA review this action consistent with existing case law, which requires cost to be considered in the promulgation of this rule.

(7) POWER! requests EPA review the full effect of this proposed rule as it relates to CERCLA's ability for parties and states to force and enforce cleanup responsibilities without action on the same by EPA.
(8) POWER! requests EPA ensure that the nation's water agencies, wastewater agencies, and municipalities are not subject to unwarranted litigation and potential liability – the costs of which will land with ratepayers.
(9) POWER! requests EPA review this proposed rule and its direct impact on the principle of CERCLA for polluters to pay for cleanups and the shift of that responsibility on ratepayers due to this proposed rule.

Thank you for the opportunity to provide comments on this proposed rule. If you have any questions or would like any additional information, please contact Ana Schwab at Ana.Schwab@BBKLaw.com.

Sincerely,

POWER!
Protecting Our Water, Environment, and Ratepayers!

POWER!
Protecting Our Water,
Environment, and Ratepayers!

Water Environment Federation®
the water quality people™
601 Wythe Street
Alexandria, Virginia USA 22314-1994
+1.703.684.2400
www.wef.org

November 7, 2022

Office of Superfund Remediation & Technology Innovation
U.S. Environmental Protection Agency
EPA Docket Center
OLEM Docket, Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: WEF's Comments on the Proposed Listing of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as Hazardous Substances Under the Federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Docket ID No. EPA-HQ-OLEM-2019-0341)

The Water Environment Federation (WEF) thanks the U.S. Environmental Protection Agency (EPA) for the opportunity to comment on the proposed listing of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as hazardous substances under the federal Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (Docket ID No. EPA-HQ-OLEM-2019-0341).

WEF is a not-for-profit association that has provided technical education and training for the world's water quality professionals since 1928. The Federation has over 30,000 individual members and 75 affiliated Member Associations who support its mission to preserve and enhance the global water environment. WEF is supportive of regulations that are science based, achievable, and protective of human health and the environment.

In general, our comments below support biosolids for beneficial and safe use and that EPA's proposal in this rulemaking is premature and lacking information that would be needed in order to proceed with a science-based rulemaking. In addition, EPA's economic analysis lacks the robustness necessary of a rulemaking having been found to be "economically significant".

Biosolids are Beneficial and Safe for Use and this Rulemaking is Premature

Public clean water utilities receive and treat a broad range of influent from heterogenous sources including domestic, industrial, and commercial sources. This influent, which is not generated by the utility, but which the utility is responsible for treating, may contain PFAS constituents ranging from trace to higher concentrations based on the nature of the dischargers connected to the sewer system. WEF's members are the primary implementers of the National Pretreatment Program, charged with controlling commercial and industrial discharges to the sewer. WEF members also have been involved in EPA and state efforts to address PFAS contamination. WEF has submitted comment letters urging the EPA to develop a federal response that appropriately

reflects the risks posed by PFAS, close the unresolved scientific gaps including fate, transport, and toxicity of PFAS using a science-based approach and evaluate the appropriate regulatory response to target the sources of PFAS and the responsible disposal of contaminated concentrate.

The Clean Water Act, established 50 years ago, was created to regulate discharges to the waters of the United States and create pollution control programs. These programs became our modern-day water resource recovery facilities, complete with required pretreatment programs, active in communities across the nation. The Act also made it a requirement to evaluate its own efficacy through annual biosolids reporting and biennial reviews of biosolids standards. With this express intent to keep waters clean through continuous and transparent program review, biosolids have been researched and regulated more than any fertilize available on the market. Biosolids, which comprise used in accordance with regulations set forward in EPA’s Part 503 Biosolids Rule and state-specific requirements, have become widely accepted by soil scientists and the agricultural sector.

In addition, WEF acknowledges that EPA is undertaking a scientific review of PFAS in biosolids by the end of 2024 that is an integral part of developing biosolids modeling tools focused on consistent and transparent risk assessments based on sound science. These assessments are the technical basis for determining whether numeric standards for chemical pollutants in biosolids are warranted under Section 405 of the Clean Water Act. Finally, the risk assessment framework that EPA is developing is scheduled to undergo EPA Science Advisory Board (SAB) review later this year. The assessments for PFOA and PFOS contamination in biosolids will consider risks associated with land application and surface disposal of biosolids, and will analyze human exposure routes, such as consumption of drinking water and food including plants, meat, and dairy, as well as environmental impacts.

In the past, EPA has long supported and promoted the longstanding practice of beneficially and sustainably using biosolids as a fertilizer. Land application of biosolids provides a valuable resource to communities by sustainably utilizing this natural, safe, and renewable resource instead of discarding it in landfills and taking up this limited landfill space. This rule ignores the impact that the CERCLA designation will have on this long-term practice and the absence of widely available alternatives. Prior to considering a CERCLA designation, it is critical that EPA review all components related to PFAS research and regulation and first develop policies that support the continued use of these products so farmers can use them with confidence. Without additional fertilizer alternatives available to our farming community, this will directly impact our farms and access to locally grown agricultural products. In addition, WEF and other partners have written letters recommending that EPA consider excluding water, wastewater and land application of biosolids from liability under CERCLA should EPA go forward with the designation in this rulemaking.

The Economic Analysis is Not Adequate for this "Economically Significant" Rulemaking

Based on a Congressional Research Service study, water and wastewater services can account for 30%-40% of the energy costs of a municipality[1] – *before* addressing PFAS. As noted in the study, energy is the second-highest budget cost item after labor cost; therefore, addressing these costs, especially as they relate to biosolids management[2] is essential for water and wastewater facilities. EPA maintains the Proposed Rule is not "economically significant," however, this may only be the case because EPA has not adequately assessed estimated costs and is supporting their position based on costs limited to reporting.

While reporting costs may not be considered "economically significant" by EPA, they still have the high probability that they can be due to the cost of preparing a report as well as the frequency of doing so. These costs will be minimal compared to the other quantitative impacts to water and wastewater systems. These impacts include the economic impacts on water systems to the extent new disposal requirements of PFOA- and PFOS-laden filtration media or biosolids will be necessary. This also includes the economic impacts arising from implication of becoming a "Potential Responsible Party" (PRP) under CERCLA. However, EPA's analysis in the Proposed Rule does not acknowledge these types of costs – costs that will ultimately be incurred by water and wastewater utilities and the public at large.

WEF is of the position that EPA must analyze these costs impacts more carefully in determining whether any final rule is "economically significant" and should be transparent in the costs that will result if the rule is finalized as proposed. In the event EPA does not conduct a more robust analysis of these costs in determining they are "economically significant" as part of the final rule, EPA must explain why these costs are not necessary for evaluation, given the functional certainty of their occurrence.

Conclusion

In the scenario that PFAS receivers do become a PRP, public health concerns surrounding access to clean water and sanitation will fast become a reality. In addition, sustainability goals meant to curb climate change such as soil health initiatives, sequestering carbon in soils, methane gas avoidance in landfills, food accessibility, local fertilizer expansion, water scarcity, renewable nutrients and energy offsets will be directly compromised.

WEF supports an intensified focus on stopping sources of PFAS contamination that utilize and build upon the established and proven pretreatment programs that are the foundation of the Clean Water Act. PFAS treatment is a fix after a failure and designating PFAS receivers as polluters is a scapegoat for the underlining issue of contaminant introduction. WEF recommends that we utilize this challenge to public

---

[1] *Energy-Water Nexus: The Water Sector's Energy Use*, Congressional Research Service (CRS, 2017); https://crsreports.congress.gov -R43200.

[2] Biosolids have been demonstrated to be more than 50% of a utility's annual budget (U.N. Habitat 2008).

health and the environment as a learning opportunity and stop contaminants from entering our delicate watersheds in the first place, including continued efforts to reduce or eliminate future PFAS contamination by incentivizing a shift away from nonessential PFAS compounds.

EPA's proposal in this rulemaking is premature and lacking information that would be needed in order to proceed with a science-based rulemaking. Finally, EPA's economic analysis lacks the robustness necessary of a rulemaking having been found to be "economically significant." As such, WEF does not support finalizing this proposed rule.

Sincerely,

Walter T. Marlowe, P.E., CAE
Executive Director
Water Environment Federation

WATEREUSE
625 First Street, #621 • Alexandria, VA 22314

November 7, 2022

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator Regan:

On behalf of the WateReuse Association (WateReuse), I am pleased to submit our comments regarding the U.S. Environmental Protection Agency's (EPA) Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances.

The WateReuse Association is a not-for-profit trade association for water utilities, businesses, non-profit organizations, and research entities that advocate for policies and programs to advance water recycling. WateReuse and its state and regional sections represent nearly 250 water utilities serving over 60 million customers, and over 200 businesses and organizations across the country.

As currently written, the proposed rule places liability burdens on receivers of PFOS and PFOA rather than on producers of the substances. Water, wastewater, and water recycling utilities (water utilities) stand ready to help tackle the PFAS crisis; however, putting the liability and cost of remediation on utilities ultimately burdens the local rate payer, and therefore, the American taxpayer, rather than the polluter.

The WateReuse Association therefore urges EPA to adopt the following recommendations to ensure that the final rule is effective and fair.

<u>Recommendation #1: WateReuse strongly urges EPA to support the creation of a narrowly tailored exclusion from PFAS CERCLA liability for water, wastewater, and water recycling facilities acting in accordance with all applicable laws.</u>

Water utilities provide essential public services and are not manufacturers or primary sources of PFAS. These water utilities protect public health and the environment while providing communities with essential services. Water recycling facilities meet additional public interest needs by generating alternative water supplies, supporting communities' climate resiliency and adaptation to the impacts of climate change. Under the proposed rule, these essential services could be undermined if water utilities are held liable for the costs of remediation under CERCLA, or if scarce public dollars are diverted to defend against litigation from other parties seeking to make local agencies financially responsible for cleanup costs.

Some water recycling facilities employ technologies such as nanofiltration (NF), reverse osmosis (RO), granulated activated carbon removal (GAC), ion exchange (IX), and PFAS-selective novel adsorbents to ensure a high-quality alternative supply of water. These technologies are also some of the most effective removal technologies for PFOA and PFOS. However, these treatment processes generate residuals, such as spent media, NF, RO concentrate (reject) streams that can include PFAS. Under CERCLA, water recycling facilities' management of the generated spent media and residuals may fall under "releases" and "disposals," exposing utilities to liability, and their ratepayers to the associated clean-up costs.

Similarly, wastewater utilities face this liability question and exposure when considering the management of biosolids. Wastewater treatment facilities produce biosolids as an unavoidable part of the treatment process, which are managed and properly disposed of through use as a soil amendment through direct land application or after composting, incineration, and landfill disposal. As managers of this material, which could potentially contain PFOA or PFOS, water utilities could be considered a potentially responsible party (PRP) under CERCLA, making them liable for the costs of cleanup.

The federal government must protect the public from bearing the brunt of PFAS cleanup liability. EPA should therefore support a clear, narrowly tailored PFAS exemption under CERLCA for water, wastewater, and water recycling utilities and agencies. If the Agency believes it does not already have the authority to include an exemption in the rule, we strongly urge the Agency to convey to Congress its support for such an exemption.

<u>Recommendation #2: EPA should conduct a comprehensive assessment of the potential costs of the proposal, including direct and indirect cleanup costs</u>.

The proposed rule fails to account for the ramifications of the designation on the water community, as evidenced by the absence of a full cost analysis. The failure to assess the impacts of cleanup liability on water utilities is a grave error, which must be corrected before the rule can proceed.

Placing the liability and cost on public utilities, ratepayers, and taxpayers undermines CERCLA's "polluters pay" model and will impact water utilities' ability to make essential capital investments to modernize infrastructure and combat climate change. Imposing CERCLA liability on water and wastewater utilities will lead to untenable cost increases and delays, significantly hampering the implementation of essential water projects needed to meet the challenge of establishing a reliable and sustainable water supply. It is essential to consider the cost this proposed rule places on local water utilities and districts; yet, EPA fails to consider this in its decision not to conduct an economic assessment of the cleanup costs and litigation costs associated with this designation.

<u>Recommendation #3: EPA should clarify how water utilities will monitor, track, and report potential releases.</u>

The proposed rule fails to consider how water utilities will be impacted by the decision to utilize the CERCLA default reportable quantity (RQ) for a hazardous substance of one or more pounds per 24-hour period. The CERCLA default RQ is not designed to be a metric monitored or tracked

by water utilities, and utilizing it fails to consider how water utilities can monitor effluent and biosolids concentrations to determine an RQ without validated test methods and sufficient lab capacities. It is not clear how the default RQ applies to the ongoing and ubiquitous nature of PFAS in water. EPA should clarify if, as well as how, this reporting structure would apply to water utilities.

Recommendation #4: WateReuse urges the federal government to invest in research and development for PFAS control and destruction technologies.

The proposed rule also fails to provide guidance on how to remediate and destroy PFOA and PFOS. With no guidelines on effective ways to manage or destroy PFAS-laden biosolids or residual streams (e.g. RO concentrate, spent GAC media), how are utilities to proceed? For EPA to create this designation, without a plan of action for the remediation or a prohibition on all uses of PFOS and PFOA (and any other PFAS compounds that EPA wishes to designate as hazardous substances) to prevent PFAS from continuing to enter water and wastewater utilities, the CERCLA designation becomes an ineffective tool for handling PFAS in water systems and simply passes the buck to local governments, and ultimately, ratepayers/taxpayers. The federal government needs to invest in conducting science-based research for PFAS control and destruction technologies to provide utilities with clear guidance moving forward.

As written, the proposed rule transfers the societal cost of clean-up and remediation from polluters to the public. It hampers utilities' ability to make essential capital investments, and it upends current practices of biosolids, media, and residual management and disposal. EPA needs to amend the proposed rule to focus on PFAS polluters and ensure that water, wastewater, and water recycling facilities are not held liable for remediation of PFAS contamination that may have unknowingly and unwittingly occurred in the normal course of providing essential public services.

We thank EPA for the continued engagement with the water stakeholder community and urge EPA to evaluate and consider potential adverse consequences of new rules, including implications for existing water recycling projects. WateReuse looks forward to working with you and your team to ensure that EPA funding programs effectively support water reuse projects across the United States.

Sincerely,

Patricia L. Sinicropi, J.D.
Executive Director

American Water Works Association
Dedicated to the World's Most Important Resource™

Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

November 7, 2022

Barry Breen
Acting Assistant Administrator
Office of Land and Emergency Management
Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Mail Code: 28221T
Washington, DC 20460
SUBMITTED ELECTRONICALLY

RE: Comments on Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances (Docket ID No: EPA-HQ-OLEM-2019-0341)

Dear Mr. Breen,

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Environmental Protection Agency (EPA or the Agency) rulemaking titled "Proposed Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA [Comprehensive Environmental Response, Compensation, and Liability Act] Hazardous Substances" (the Proposal). Our members strive to protect public health through unfailing operation of drinking water systems and domestic and municipal sewage treatment, AWWA therefore has an active interest in effective and lawful leveraging of the EPA's authorities to address the challenges arising from per- and polyfluoroalkyl substances (PFAS).

AWWA is concerned that the Proposal imposes significant costs and long-term liability on drinking water and domestic sewage treatment facilities (herein referred to collectively as water systems) and threatens to compound financial burdens on water systems that are, or under a forthcoming rule will be, protecting public health through drinking water treatment of PFOA and PFOS. These burdens will be directly felt by the water systems' ratepaying customers and felt most acutely by those living in environmental justice communities.

While the Proposal does not list drinking water systems as "potentially affected entities" this Proposal could impose liability on the nearly 144,000 drinking water systems in addition to 19,000 domestic wastewater treatment systems across the United States, given the widespread presence of PFOA and PFOS in the environment (EPA, 2022a; EPA, 2022b). This liability will cause waste management costs for water systems to increase, which may have upwards of a $3.5 billion annual impact (Hazen & Sawyer, 2022). Those costs will have a direct impact on our members and their customers.

The Agency, in press releases and public outreach meetings, has signaled an interest in working to address equity concerns for water systems and other similarly innocent parties financed through ratepayers and taxpayers as it addresses PFAS-related concerns (EPA, 2022c; EPA, 2022d). As a key stakeholder representing members working on the frontlines of these pressing issues, AWWA appreciates the Agency shares these concerns. AWWA writes to explain why the Proposal will negatively impact water systems in a way that is not consistent with the Proposal's objectives or the EPA's stated concerns. AWWA has prepared the following comments and is attaching a legal

Under the Proposal, each of these waste streams is at risk of being the target for future lawsuits and subsequent cleanup liability, regardless of the relative contribution of PFOA and PFOS to the site. While most of these waste streams are unlikely to be subject to the reporting requirements, potentially responsible parties (PRPs) brought into CERCLA litigation by the EPA could target water systems for these waste streams regardless of the levels of PFOA and PFOS present. Even with enforcement discretion framed up in the proposal by the EPA, examples of water systems and municipalities historically being sued by PRPs has demonstrated that water systems may expend significant funds in litigation costs and that the EPA is incapable of shielding these systems. These legal fees, and the threat of liability will consume a considerable level of ratepayer and taxpayer funding that should otherwise be directed to infrastructure investment. This liability will threaten the long-term stability and financial capacity of water systems that provide critical infrastructure services for the public and the national economy.

Shifting the Landscape of Water Treatment Residual Management

As acknowledged by the Proposal, the rule is expected to lead to "better waste management and/or treatment by facilities handling PFOA or PFOS." The creation of liability for PFAS-containing wastes will drive changes in not only how these wastes will be managed but whether certain waste management approaches are available and the availability of recycled waste materials for treatment. AWWA members have begun reporting that the proposed designation of PFOA and PFOS as hazardous substances is already having impacts on typical operations. The Proposal neglects to quantify these impacts, despite data being widely available.

A survey of unit costs for residuals management by Hazen and Sawyer was recently conducted and found that the costs of hazardous waste disposal was 10 to 50 times more expensive compared to land application disposal of biosolids (Hazen & Sawyer, 2022). In fact, EPA's Interim Guidance on Disposal of PFAS Wastes estimated that incineration of liquid sludges, like those generated by water treatment plants may cost upwards of $1,700 per ton (EPA, 2020). Another report released in October 2020 provides an analysis of various case studies where policy and regulation of PFAS in biosolids drove changes in management and disposal (CDM Smith, 2020). Hazen & Sawyer estimates that the economic impact of a CERCLA designation causing a shift in waste management from typical practice at present to hazardous waste incineration is more than $3.5 billion (Hazen & Sawyer, 2022).

The analysis notes a marked increase of 80 to 230% in biosolid management costs. As noted in the study, biosolids management costs typically represents 8-17% of total operating costs, which when increased this dramatically will have significant impacts on water rates.

The EPA estimates that more than 4.5 million dry metric tons of wastewater biosolids are produced on an annual basis, more than 40% of which are land applied (EPA, 2022f). According to the Water Environment Federation (WEF), the average person generates about 37 pounds of biosolids annually, collectively 5.8 million dry tons each year (WEF, 2022; NBDP, 2022a). It is also estimates that 2.3 million dry tons of biosolids are used by agriculture; in fact, 29 states used more than half of their biosolids for beneficial use (NBDP, 2022a; NBDP, 2022b). On the drinking water side, residuals are generated by various types of drinking water processes such as conventional treatment (coagulation, flocculation, and sedimentation) as well as other processes like lime softening. Research has shown that PFAS can be removed, albeit ineffectively, by these processes (Xiao, 2012; Belkouteb, 2020; Zhang, 2021; Cornelson, 2021). The potential for PFAS to be present in conventional treatment residuals increases with the use of powder activated carbon prior to sedimentation. There are some vendors that are also working to develop coagulants that aid in the removal of PFAS, such as PerfluorAd (TRS Group, 2020). Given that CERCLA

Environmental Science & Technology Letters

pubs.acs.org/journal/estlcu

Letter

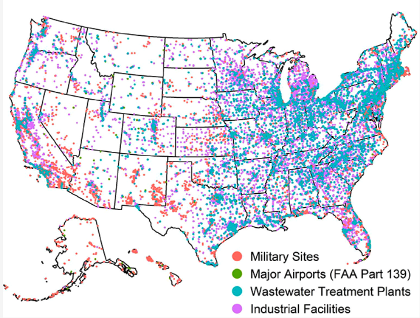
Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources

Derrick Salvatore, Kira Mok, Kimberly K. Garrett, Grace Poudrier, Phil Brown, Linda S. Birnbaum, Gretta Goldenman, Mark F. Miller, Sharyle Patton, Maddy Poehlein, Julia Varshavsky, and Alissa Cordner*

Cite This: *Environ. Sci. Technol. Lett.* 2022, 9, 983−990

Read Online

ABSTRACT: While research and regulatory attention to per- and polyfluoroalkyl substances (PFAS) has increased exponentially in recent years, data are uneven and incomplete about the scale, scope, and severity of PFAS releases and resulting contamination in the United States. This paper argues that in the absence of high-quality testing data, *PFAS contamination can be presumed* around three types of facilities: (1) fluorinated aqueous film-forming foam (AFFF) discharge sites, (2) certain industrial facilities, and (3) sites related to PFAS-containing waste. While data are incomplete on all three types of presumptive PFAS contamination sites, we integrate available geocoded, nationwide data sets into a single map of presumptive contamination sites in the United States, identifying 57,412 sites of presumptive PFAS contamination: 49,145 industrial facilities, 4,255 wastewater treatment plants, 3,493 current or former military sites, and 519 major airports. This conceptual approach allows governments, industries, and communities to rapidly and systematically identify potential exposure sources.



KEYWORDS: *per- and polyfluoroalkyl substances (PFAS), presumptive contamination, PFAS testing and investigation, AFFF, PFAS waste and disposal*

INTRODUCTION

Per- and polyfluoroalkyl substances (PFAS) are a class of over 12,000 chemicals widely used in consumer and industrial applications.[1,2] With production origins in the U.S. Manhattan Project, manufacturers have known of health risks of certain PFAS since the 1960s.[3−5] There is growing attention to PFAS as a chemical class because many share similar adverse health effects, modes of action, and physical and biochemical properties.[6−8] PFAS are present in at least 200 use categories ranging from aerosol propellants to wire insulation.[9] Many PFAS are highly mobile in ground and surface water, and contamination of drinking water, air, and other media is a growing concern.[10] The economic and social impacts of PFAS contamination include health impacts, testing and remediation costs, agricultural and real estate impacts, and burdens on local and state governments.[11,12]

An estimated 200 million U.S. residents receive PFAS-contaminated drinking water, and state-level testing indicates widespread contamination of environmental media,[13] yet tremendous data gaps exist related to PFAS contamination and human exposure.[2,14] The only federal drinking water testing initiative with PFAS data to date, the Environmental Protection Agency's (EPA) Unregulated Contaminant Monitoring Rule 3 (UCMR3), focused on large drinking water systems, had high reporting thresholds (10−90 ng/L), and excluded private wells.[15] The EPA has developed nonbinding Health Advisory Levels (HALs) for four PFAS, including updated HALs for PFOA and PFOS at "near zero" levels,[16] but no federal limits on PFAS in public drinking water currently exist.[2]

To date, 19 states have enacted guidance or regulatory limits on PFAS in drinking water, and others have policies in development.[17] Some states have systematically tested drinking water and then looked "upstream" for contamination sources; while this approach provides substantial data, it is time-consuming, resource-intensive, excludes PFAS not commonly analyzed, and potentially misses contamination that has not yet reached drinking water sources. State agencies differ in levels of relevant expertise and face disincentives to testing for PFAS without a mandate, including testing costs, liability concerns, risk communication challenges, time and resource constraints, and remediation challenges.[11] Thus, *known* PFAS contami-

Received: July 19, 2022
Revised: August 17, 2022
Accepted: August 19, 2022
Published: October 12, 2022

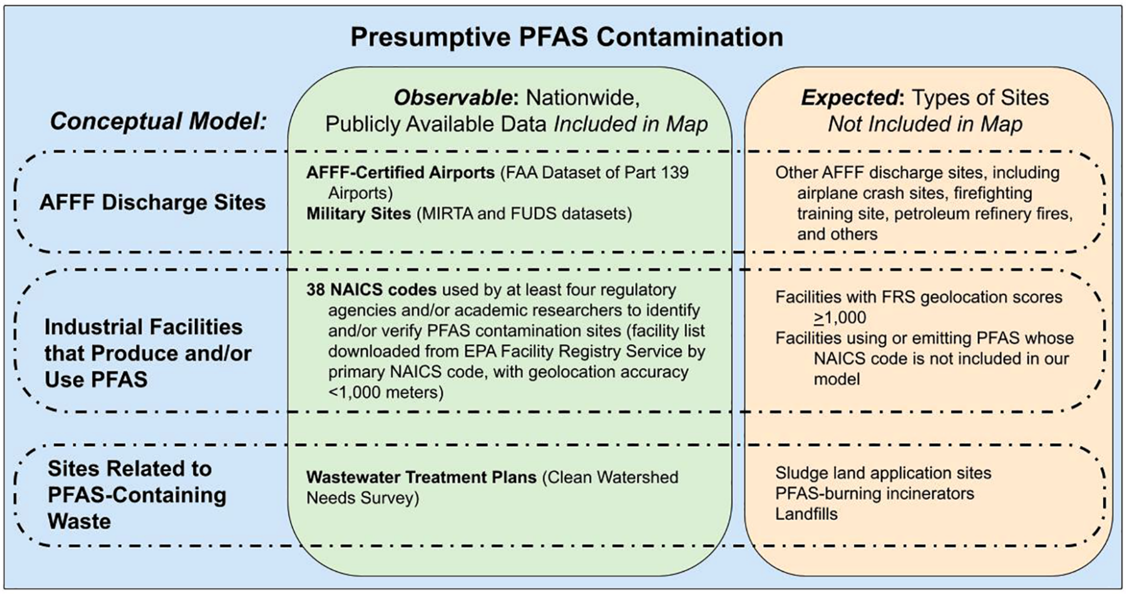


Figure 1. Conceptual framework of presumptive contamination.

nation underrepresents the scope of contamination and is biased toward locations with rigorous testing programs.

In the absence of comprehensive testing data, locations of *presumptive PFAS contamination* can be identified based on proximity to certain types of identified facilities. Proximity to contamination is consistently associated with higher PFAS levels in drinking water, and consuming contaminated water is associated with higher PFAS blood levels.[18,19] Our analysis builds on prior research identifying suspected industrial PFAS dischargers,[20] state-based studies that use PFAS testing data to identify suspected categories of contamination,[18] self-reported PFAS release data from industrial users,[21] and numerous studies on specific PFAS-contaminated sites.

This paper presents a *conceptual argument* for presumptive contamination and a *methodological approach* that conservatively identifies specific locations of likely contamination to guide interventions, resulting in a publicly available map of presumptive PFAS contamination locations in the United States. Absent high-quality sampling data, agencies can use this approach to prioritize investigative testing and remediation resources, and interested stakeholders in can identify their proximity to potential PFAS contamination.

■ PRESUMPTIVE PFAS CONTAMINATION

A presumptive contamination approach posits that, in the absence of high-quality data to the contrary, PFAS contamination is probable near facilities known to produce, use, and/or release PFAS, and to protect public health, the existence of PFAS in these locations should be presumed until high-quality testing data is available. The goal of this approach is not to identify every *possible* location of PFAS contamination but rather to develop a *conservative and actionable model* based on the best available data regarding sources of PFAS contamination. Several state and federal agencies already use a similar model that targets sampling for PFAS contamination based on facility type.[22,23]

Existing research suggests that in the absence of high-quality testing, the potential for PFAS contamination should be presumed at three types of sites: (1) AFFF discharge sites; (2) certain industrial facilities; and (3) sites related to PFAS-containing waste (Figure 1). As we discuss below, publicly available, high-quality, nationwide data exists for some, but not all, of these facility types ("Observable" in Figure 1). Other types of sites described by our conceptual model lack high-quality, nationwide data sets, so they are not included in our map ("Expected" in Figure 1).

1. AFFF Discharge Sites. Fluorinated AFFF has been used extensively for fire training and extinguishing fuel-based fires.[24] PFAS contamination is expected wherever AFFF has been discharged, including military sites, major airports, fire training areas, and some fire suppression locations.

Military Sites. AFFF has been routinely discharged at Department of Defense (DOD) sites since 1967 as part of training, testing, and firefighting operations.[25] Numerous military installations remain unassessed, including many Formerly Used Defense Sites (FUDS) abandoned or returned to private or public use.[26]

Major Airports. Airports serving scheduled carrier operations with more than nine seats require certification under Title 14 Code of Federal Regulation Part 139, which includes regular testing and AFFF discharge.[27] In 2018, Congress directed the Federal Aviation Agency (FAA) to stop requiring fluorinated AFFF use by 2021,[28] but no fluorine-free foams have been certified by DOD.[24] Airports continue to use fluorinated AFFF, though training activities no longer necessarily result in fluorinated AFFF releases.[27]

Other Firefighting Training Sites. PFAS contamination is expected at locations where AFFF was discharged during firefighting training.[24] Since 2018, 13 states have legislatively restricted the use of fluorinated AFFF for training and testing,[29] and fire departments elsewhere have voluntarily stopped using AFFF in training, though storage and disposal concerns remain.[30] In 2020, DOD released guidance prohibiting AFFF use in testing and training at most facilities.[31]

High-Hazard Flammable Liquid Fire Sites. PFAS contamination should also be expected at fire suppression locations where fluorinated AFFF was deployed. Although airplane crashes are rare and the majority take place at or near

airports,[32] AFFF would be expected to be discharged.[24] Additionally, AFFF is used to extinguish fires at railroad crash sites, oil and gas extraction sites, petroleum refineries, bulk storage facilities, and chemical manufacturing plants.[24,33]

2. Industrial Facilities That Produce and/or Use PFAS. PFAS are used in numerous manufacturing and industrial processes.[9] The EPA requires facilities in certain industries to report the release or treatment of 175 nonproprietary PFAS, mostly PFAS included in the EPA's PFOA Stewardship Program and/or existing Significant New Use Rules, to the Toxics Release Inventory (TRI).[21] In 2020, only 39 unique facilities reported PFAS TRI emissions, likely a huge underestimation.[34] Thus, TRI disclosures are an incomplete portrait of PFAS emissions, and facility type is a better predictor of PFAS discharges.

Industrial facilities are identified by North American Industry Classification System (NAICS) codes.[35] Researchers, state environmental agencies, and the EPA have all used NAICS codes to identify facilities suspected of using PFAS, although approaches vary.[18,20,36−44] Our method, described below, synthesizes previous approaches into a single set of NAICS codes that are likely sources of PFAS contamination.

3. Sites Related to PFAS-Containing Waste. PFAS are often present in wastewater, resulting in contaminated effluent and sludge from wastewater treatment plants (WWTPs).[18,45] When WWTP sludge is applied to agricultural land, it can contaminate soil and agricultural products.[46] Facilities handling solid waste can generate additional PFAS-contaminated media, such as landfill leachate or incinerator ash.[47] Complete combustion of certain PFAS requires a minimum temperature of 1000 °C, raising concerns about airborne emissions from incinerators.[48,49]

■ MATERIALS AND METHODS

Identifying all locations of presumptive PFAS contamination would require high-quality, nationwide data for the three categories of sites described above. In the absence of such data, we combined available public data sets described below into a single spatial analysis.

We identified *Military Sites* using the Military Installations, Ranges, and Training Areas (MIRTA) data set from the DOD's Defense Installations Spatial Data Infrastructure Program (retrieved from U.S. Army Corps of Engineers Geospatial Open Data)[50] and the FUDS data set from the DOD's Defense Environmental Restoration Program Annual Report to Congress (retrieved from U.S. Army Corps of Engineers Geospatial Open Data).[51] We filtered the FUDS data set to only include FUDS with at least one cleanup "project".

We identified *Major Airports* by downloading the FAA Part 139 Airport Certification Status Table data set.[52] We assigned coordinates for each AFFF-certified airport using a Google Maps API.

We identified 11 lists of *Industrial Facility* NAICS codes previously used by regulatory agencies and academic researchers to link PFAS contamination to facility type: the primary NAICS codes of facilities reporting TRI PFAS emissions,[53] NAICS codes used in two academic studies that quantitatively linked facility type to PFAS contamination,[18,38] and NAICS codes from eight regulatory lists used for testing and site prioritization by state or federal agencies.[36,37,39−44] To reliably identify industry facilities that are presumptive sources of PFAS contamination across the resulting 191 distinct NAICS codes, we included only 38 NAICS codes that were present on at least four lists (Table S-1).

Data about facilities self-reporting within these NAICS codes were downloaded from the EPA's Facility Registry Service (FRS) EZ Query.[54] To remove poorly geocoded data, we excluded 23.5% of industrial facilities (n = 21,316) with FRS geolocation accuracy scores ≥1,000 m or missing geolocation data. Included NAICS codes also capture some AFFF discharge sites, including petroleum refineries, and some sites related to PFAS-containing waste, including solid waste landfills and incinerators.

We identified *WWTPs* using the Clean Watershed Needs Survey, which collected nutrient load data every four years from 1972 to 2012.[55] These data were downloaded and filtered to include only "major" WWTPs, which have a design flow of ≥1 million gallons per day or an industrial pretreatment program.[56]

High-quality, nationwide data on many other presumptive contamination sites, including locations of firefighting training, airplane and railroad crashes, and sludge application, are not publicly available.

Analysis. Analysis was conducted using R version 4.1.2[57] and RStudio version 2021.09.2.[58] Presumptive contamination sites were combined into a single data set. We transformed all coordinates to match a uniform reference system (NAD83) and removed sites with duplicate entries or missing geocoded information. We downloaded the U.S. Census Bureau's Cartographic Boundary shapefile for states,[59] and used the R package *sf*[60] to locate each site within states. The PFAS Project Lab, Silent Spring Institute, and PFAS-REACH maintain an interactive map in ArcGIS Experience Builder to visually display sites of presumptive contamination.[61] Unlike some existing PFAS screening tools,[41] we did not assign any weighting to site types.

We used a manual validation process to assess whether our conceptual model fully captured known PFAS contamination sites. Briefly, we identified known PFAS contamination sites using the PFAS Project Lab's PFAS Contamination Site Tracker.[61,62] To be conservative in our validation process, our validation method prioritized locations with more PFAS testing. We selected four counties from each of the five states with the highest numbers of known contamination sites and the five states closest to the median number of known contamination sites. For each of the selected 40 counties, we searched the presumptive contamination data set for sites that were in the known contamination data set.[61] We calculated three accuracy measurements in our validation process: the percent of known contamination sites that were captured by our presumptive contamination data set (*observed*); the percent of known contamination sites that were included in our conceptual model but were not captured by our data set (*expected*); and the percent of total known contamination sites (*observed* or expected) that were included in our data set or our conceptual model (*total*).

The Supporting Information Document accompanying this paper includes a justification for and in-depth description of this validation process, as well as additional details regarding validation in New Hampshire. Table S-1 lists the 38 NAICS codes included in our presumptive contamination model. Table S-2 presents county-level results from our validation model, Table S-3 separates validation results by states with high versus median number of known contamination sites, and Table S-4 separates validation results by counties with high

https://doi.org/10.1021/acs.estlett.2c00502
Environ. Sci. Technol. Lett. 2022, 9, 983−990

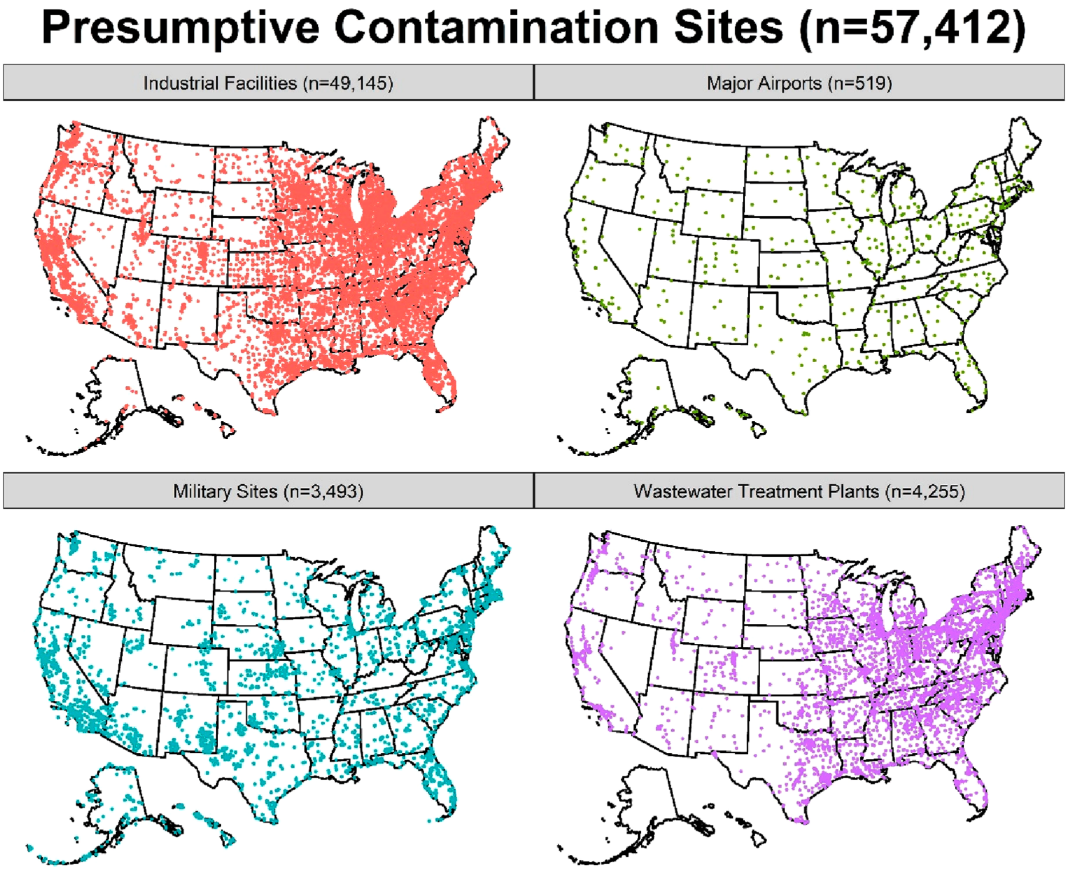


Figure 2. Map of presumptive contamination sites identified using presumptive contamination model.[61]

versus median number of known contamination sites. Table S-5 presents validation results excluding known contamination sites from New Hampshire. Table S-6 includes site-by-site validation results for 503 sites.

RESULTS AND DISCUSSION

We identified 57,412 sites of presumptive PFAS contamination in the United States, including 49,145 industrial facilities, 4,255 WWTPs, 3,493 military sites (762 MIRTA and 2,731 FUDS), and 519 major airports (Figure 2). These sites are displayed in the publicly available PFAS Contamination Site and Community Resources map (available at www.pfasproject.com).[61]

Our validation sample included 503 known contamination sites from 40 counties in 10 states. Of these, 176 (35%) were *observed* in the map, and another 187 (37%) were *expected* by the model but were not mapped due to data limitations, bringing the total validation accuracy to 72% (Table 1, Table S-2). The 28% of known contamination sites not captured by our model were generally of three types: (1) sites where PFAS contamination is comprehensible but whose NAICS codes are not presumptive within our conservative model, including septage businesses, car washes, and textile cleaners; (2) sites not logically associated with PFAS contamination, such as convenience stores, senior centers, and restaurants; and (3) sites with relatively low levels of PFAS, perhaps suggesting background contamination rather than a specific source. A full list of all 503 sites and their classification is available in Table S-6.

As expected, our conceptual model was more predictive in locations with median levels of known PFAS contamination (Table S-3 and S-4). Accuracy varied by state, reflecting differences in testing approaches. For example, New Hampshire's robust PFAS testing has identified 469 known contamination sites, while our model identifies only 380 presumptive sites (Table S-5).

Our nationwide map provides an underestimation of presumptive PFAS contamination because of data quality and availability issues. 23.5% of identified industrial facilities (n = 21,316) were excluded because they lacked high-quality geolocation information. NAICS codes are self-reported, leading to possible misclassification. Despite being documented as possible PFAS sources, other facilities that likely produce or use PFAS are also excluded, such as dry cleaners, car washes, or ski shops, because we are not confident that every facility of its type should be considered presumptive. For example, although some dry cleaning processes use and release PFAS,[63] other dry cleaners are water-based or send cleaning to off-site facilities, so including all dry cleaners would be inappropriate.

High-quality nationwide data on other sites of presumptive PFAS contamination, including firefighting training sites, railroad and airplane crash sites with AFFF use, oil and gas hydraulic fracturing sites, bulk fuel storage facilities, and sewage sludge application sites, are not publicly available. Our map also excludes U.S. territories because of data limitations. State and local efforts have developed data on additional presumptive contamination sites that are not included in this nationwide map.[46,64−67] Subnational analyses could incorpo-

https://doi.org/10.1021/acs.estlett.2c00502
Environ. Sci. Technol. Lett. 2022, 9, 983−990

Table 1. Presumptive Contamination Model Validation by Selected States[a,f]

State	Known contamination sites, *n*	Consolidated county known contamination[b]	Known contamination sites, *n*	Observed matches[c], *n* (%)	Expected matches (not observed)[d], *n* (%)	Total matches[e], *n* (%)
New Hampshire	469	2 Highest	189	30 (16%)	69 (37%)	99 (52%)
		2 Median	76	14 (18%)	32 (42%)	46 (61%)
California	253	2 Highest	52	39 (75%)	11 (21%)	50 (96%)
		2 Median	8	6 (75%)	2 (25%)	8 (100%)
Michigan	188	2 Highest	57	30 (53%)	22 (39%)	52 (91%)
		2 Median	2	0 (0%)	2 (100%)	2 (100%)
Minnesota	101	2 Highest	17	9 (53%)	6 (35%)	15 (88%)
		2 Median	2	2 (100%)	0 (0%)	2 (100%)
Maine	99	2 Highest	28	9 (32%)	11 (39%)	20 (71%)
		2 Median	11	2 (18%)	7 (64%)	9 (82%)
Vermont	62	2 Highest	30	15 (50%)	15 (50%)	30 (100%)
		2 Median	7	2 (29%)	5 (71%)	7 (100%)
Mississippi	9	2 Highest	5	5 (100%)	0 (0%)	5 (100%)
		2 Median	2	2 (100%)	0 (0%)	2 (100%)
Rhode Island	8	2 Highest	5	1 (20%)	3 (60%)	4 (80%)
		2 Median	3	2 (67%)	1 (33%)	3 (100%)
Washington	8	2 Highest	2	2 (100%)	0 (0%)	2 (100%)
		2 Median	2	1 (50%)	1 (50%)	2 (100%)
Tennessee	6	2 Highest	3	3 (100%)	0 (0%)	3 (100%)
		2 Median	2	2 (100%)	0 (0%)	2 (100%)
Total			503	176 (35%)	187 (37%)	363 (72%)

[a]**Notes**: All county results included in Table S2. [b]Consolidated data from two counties with the highest and two counties with the median levels of known contamination sites within the state. [c]Number of presumptive contamination sites with matched known contamination sites within the counties. [d]Number of known contamination sites without presumptive contamination matches but are included in model parameters. [e]Total known contamination sites incorporated by model parameters (observed matches + expected matches). Percentages may not add to 100 due to rounding. [f]**Sources**: Author's analysis.[61,62]

rate additional data sets, and decision-makers should seek all available data on PFAS contamination sites in their geographic regions.

Our presumptive contamination data set excludes known PFAS contamination sites because the model's purpose is to fill data gaps and drive future surveillance and action. Because testing requirements and technical capacity of PFAS contamination vary between states, the identification of known contamination reflects the scale of testing conducted in that state, not necessarily the extent of underlying PFAS contamination. We also did not include facilities with TRI discharge reports as presumptive PFAS contamination sites, though our data set captures 32 of the 39 unique facilities that reported PFAS emissions to EPA in 2020. (The seven TRI-reporting facilities not identified by our model include facilities related to cement, fertilizer, industrial gas, analytical laboratory instruments, and fats/oils refining and blending.)

Applications and Next Steps. PFAS contamination may increase exposure for proximate populations. By developing the concept of presumptive contamination and validating that model against known contamination sites, this paper provides a rigorous advancement to previous academic and regulatory models using NAICS codes alone or in limited geographic areas. This standardized methodology allows researchers, regulators, and other decision-makers at various geographic scales to identify presumptive PFAS contamination using publicly available data, addressing several "urgent questions" described by leading PFAS scholars, including the identification of PFAS contamination hotspots and the need for accessible PFAS measurement tools.[49]

State and federal agencies can use a presumptive contamination approach to identify and prioritize locations for monitoring, regulation, and remediation. Decision-makers working at smaller geographic scales could conduct site-by-site verification of sites excluded from our data set due to poor geolocation, potentially locating many for inclusion in local efforts. Future prioritization could evaluate PFAS risks associated with facility type and/or density of sites. For example, the Minnesota Pollution Control Agency evaluates facility types codes on a scale of 1−4 based on assessed likelihood of PFAS use.[41] Additional research could determine the proximity of presumptive contamination sites to prioritized locations, such as public water supplies, Tribal lands, environmental justice communities, public parks, and population-dense areas.

While all data described in this analysis are publicly available, other PFAS data are hard to utilize, inaccessible to the public, or not nationally aggregated. We recommend that federal and state agencies develop, aggregate, and broadly disseminate information on the many sources of presumptive PFAS contamination identified in this paper. Planned nationwide testing for PFAS in public drinking water sources[68] will exclude the 43 million U.S. residents who rely on private wells.[69] States can use PFAS-specific task forces and investigative orders to identify contamination and target action using our presumptive contamination categories. Surveys to facilities identified by NAICS codes could investigate PFAS use and inform further testing and action. When nationwide data sets do not exist, local and/or state data on permits, industrial activity, and application sites could be aggregated.

Our presumptive contamination approach focuses only on proximity to locations of PFAS use, release, or disposal, ignoring other exposure routes including occupation, diet, or consumer products. Future research could expand this site-

based model to residence- and occupation-based models of presumptive *exposure*, similar to existing models of occupation-based presumptive *illness*.[70−74] Since NAICS codes can identify industries where workers are likely exposed, our approach can support occupational exposure monitoring. Identification of PFAS in consumer products could further inform an occupation-based presumptive exposure model.

In the absence of widespread testing data, this presumptive contamination model allows governments, industries, and communities to identify potential sources expeditiously and take data-informed steps to investigate and address PFAS contamination. While the scale of presumptive contamination we identified is large, it likely underestimates PFAS contamination in the United States. The high costs of PFAS contamination to human health, municipalities, and the environment demand swift regulation, reformulation, and exposure reduction.[11]

■ ASSOCIATED CONTENT

Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acs.estlett.2c00502.

> Description of Presumptive Contamination Validation Process; Table S-1. NAICS codes included in presumptive contamination model; Table S-2. Presumptive contamination model validation, county level analysis; Table S-3. Presumptive model validation, state comparison by known contamination level; Table S-4. Presumptive model validation, county comparison by known contamination level; Model Validation discussion; Table S-5. Presumptive contamination model validation, county level analysis, excluding New Hampshire; Table S-6. Presumptive contamination model validation − known contamination data (PDF)

■ AUTHOR INFORMATION

Corresponding Author

Alissa Cordner − *Department of Sociology, Whitman College, Walla Walla, Washington 99362, United States;* orcid.org/0000-0001-5223-2848; Email: cordneaa@whitman.edu

Authors

Derrick Salvatore − *Department of Marine and Environmental Sciences, Northeastern University, Boston, Massachusetts 02215, United States;* orcid.org/0000-0003-3909-9311

Kira Mok − *Department of Sociology and Anthropology and Department of Health Sciences, Northeastern University, Boston, Massachusetts 02215, United States;* orcid.org/0000-0003-4289-819X

Kimberly K. Garrett − *Department of Sociology and Anthropology and Department of Health Sciences, Northeastern University, Boston, Massachusetts 02215, United States*

Grace Poudrier − *Department of Sociology and Anthropology and Department of Health Sciences, Northeastern University, Boston, Massachusetts 02215, United States;* orcid.org/0000-0001-5568-3062

Phil Brown − *Department of Sociology and Anthropology and Department of Health Sciences and Department of Health Sciences, Northeastern University, Boston, Massachusetts 02215, United States*

Linda S. Birnbaum − *National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina 27709, United States; Duke University, Durham, North Carolina 27708, United States*

Gretta Goldenman − *Milieu Consulting, 1060 Brussels, Belgium*

Mark F. Miller − *National Institute of Environmental Health Sciences and U.S. Public Health Service, Research Triangle Park, North Carolina 27709, United States*

Sharyle Patton − *Health and Environment Program, Commonweal, Bolinas, California 94924, United States*

Maddy Poehlein − *PFAS Project Lab, Northeastern University, Boston, Massachusetts 02215, United States*

Julia Varshavsky − *Department of Health Sciences and Department of Civil and Environmental Engineering, Northeastern University, Boston, Massachusetts 02215, United States*

Complete contact information is available at: https://pubs.acs.org/10.1021/acs.estlett.2c00502

Funding

We acknowledge funding from the National Science Foundation (SES-1827817 and SES-2120510: P.B., A.C., K.M., G.P., and D.H.S.), the National Institute of Environmental Health Sciences (2-T32-ES023769-06 and R01ES028311: P.B. and G.P.), the Marisla Foundation (S.P.); and the Tides Foundation (TF2101-096968; G.G., S.P., and D.H.S.).

Notes

The authors declare no competing financial interest.

■ ACKNOWLEDGMENTS

We are grateful to the Reviewers and Editor for thoughtful comments that greatly improved this manuscript, including the suggestion of validating known contamination sites. We are grateful to Andrew Lindstrom for invaluable comments and suggestions, and to Laurel Schaider, Courtney Carignan, Maia Fitzstevens, Alex Goho, and Erik Haugsjaa for collaborative work on the PFAS Sites and Community Resources map. We are grateful to members of the PFAS Project Lab, including Lauren Richter, Jennifer Ohayon, Rosie Mueller, Marina Atlas, Miranda Dodson, Lilyana Ibañez, and Mya Heard, for their support of this project.

■ REFERENCES

(1) U.S. EPA. *CompTox Chemicals Dashboard | PFASMASTER Chemicals*. https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster (accessed 2021−11−11).

(2) U.S. EPA. *PFAS Strategic Roadmap: EPA's Commitments to Action 2021−2024*. https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 (accessed 2021−11−11).

(3) Richter, L.; Cordner, A.; Brown, P. Non-Stick Science: Sixty Years of Research and (In)Action on Fluorinated Compounds. *Soc. Stud. Sci.* **2018**, *48*, 691−714.

(4) Hounshell, D. A.; Smith, J. K. *Science and Corporate Strategy: Du Pont R and D, 1902−1980*; Cambridge University Press, 1988.

(5) Altman, R. *Time-bombing the future*; Aeon. https://aeon.co/essays/how-20th-century-synthetics-altered-the-very-fabric-of-us-all (accessed 2021−11−11).

(6) Kwiatkowski, C. F.; Andrews, D. Q.; Birnbaum, L. S.; Bruton, T. A.; DeWitt, J. C.; Knappe, D. R. U.; Maffini, M. V.; Miller, M. F.; Pelch, K. E.; Reade, A.; Soehl, A.; Trier, X.; Venier, M.; Wagner, C.

C.; Wang, Z.; Blum, A. Scientific Basis for Managing PFAS as a Chemical Class. *Environ. Sci. Technol. Lett.* **2020**, 7 (8), 532−543.

(7) Bălan, S. A.; Mathrani, V. C.; Guo, D. F.; Algazi, A. M. Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program. *Environ. Health Perspect.* **2021**, *129* (2), 025001.

(8) Cousins, I. T.; DeWitt, J. C.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Ng, C. A.; Scheringer, M.; Wang, Z. The High Persistence of PFAS Is Sufficient for Their Management as a Chemical Class. *Environ. Sci. Process. Impacts* **2020**, *22* (12), 2307−2312.

(9) Glüge, J.; Scheringer, M.; Cousins, I. T.; DeWitt, J. C.; Goldenman, G.; Herzke, D.; Lohmann, R.; Ng, C. A.; Trier, X.; Wang, Z. An Overview of the Uses of Per- and Polyfluoroalkyl Substances (PFAS). *Environ. Sci. Process. Impacts* **2020**, *22* (12), 2345−2373.

(10) Evich, M. G.; Davis, M. J.; McCord, J. P.; Acrey, B.; Awkerman, J. A.; Knappe, D. R.; Lindstrom, A. B.; Speth, T. F.; Tebes-Stevens, C.; Strynar, M. J.; et al. Per-and Polyfluoroalkyl Substances in the Environment. *Science* **2022**, *375* (6580), eabg9065.

(11) Cordner, A.; Goldenman, G.; Birnbaum, L. S.; Brown, P.; Miller, M. F.; Mueller, R.; Patton, S.; Salvatore, D. H.; Trasande, L. The True Cost of PFAS and the Benefits of Acting Now. *Environ. Sci. Technol.* **2021**, *55* (14), 9630−9633.

(12) Obsekov, V.; Kahn, L. G.; Trasande, L. Leveraging Systematic Reviews to Explore Disease Burden and Costs of Per- and Polyfluoroalkyl Substance Exposures in the United States. *Expo Health.* **2022**. https://doi.org/10.1007/s12403-022-00496-y.

(13) Andrews, D. Q.; Naidenko, O. V. Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States. *Environ. Sci. Technol. Lett.* **2020**, 7 (12), 931−936.

(14) Richter, L.; Cordner, A.; Brown, P. Producing Ignorance through Regulatory Structure: The Case of per-and Polyfluoroalkyl Substances (PFAS). *Sociol. Perspect.* **2021**, *64* (4), 631−656.

(15) U.S. EPA. *Third Unregulated Contaminant Monitoring Rule.* https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule (accessed 2021−11−11).

(16) U.S. EPA. *Drinking Water Health Advisories for PFOA and PFOS.* https://www.epa.gov/sdwa/drinking-water-health-advisories-pfoa-and-pfos (accessed 2022−07−14).

(17) Interstate Technology Regulatory Council. *PFAS Water and Soil Values Table Excel File*, 2021.

(18) Hu, X. C.; Andrews, D. Q.; Lindstrom, A. B.; Bruton, T. A.; Schaider, L. A.; Grandjean, P.; Lohmann, R.; Carignan, C. C.; Blum, A.; Balan, S. A.; Higgins, C. P.; Sunderland, E. M. Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. *Environ. Sci. Technol. Lett.* **2016**, *3* (10), 344−350.

(19) Post, G. B. Recent US State and Federal Drinking Water Guidelines for Per- and Polyfluoroalkyl Substances. *Environ. Toxicol. Chem.* **2021**, *40* (3), 550−563.

(20) Andrews, D. Q.; Hayes, J.; Stoiber, T.; Brewer, B.; Campbell, C.; Naidenko, O. V. Identification of Point Source Dischargers of Per- and Polyfluoroalkyl Substances in the United States. *AWWA Water Sci.* **2021**, *3* (5), e1252.

(21) U.S. EPA. Implementing Statutory Addition of Certain Per- and Polyfluoroalkyl Substances (PFAS) to the Toxics Release Inventory Beginning With Reporting Year 2021. *Federal Register*. https://www.federalregister.gov/documents/2021/06/03/2021-11586/implementing-statutory-addition-of-certain-per--and-polyfluoroalkyl-substances-pfas-to-the-toxics (accessed 2021−12−03).

(22) Alabama Department of Environmental Management. *ADEM Announces Precedent-Setting Consent Order with 3M*, 2020.

(23) North Carolina Department of Environmental Quality. *Chemours Signed Consent Order*, 2019.

(24) Interstate Technology Regulatory Council. *Aqueous Film-Forming Foam (AFFF)*, 2020.

(25) U. S. Government Accountability Office. *Firefighting Foam Chemicals: DOD Is Investigating PFAS and Responding to Contamination, but Should Report More Cost Information.* https://www.gao.gov/products/gao-21-421 (accessed 2021−11−11).

(26) U.S. Army Corps of Engineers. *Formerly Used Defense Sites.* https://www.usace.army.mil/missions/environmental/formerly-used-defense-sites/ (accessed 2021−11−11).

(27) Federal Aviation Administration. *Federal Aviation Administration National Part 139 CertAlert*, 2019.

(28) Guthrie, B. *FAA Reauthorization Act of 2018*, 2018.

(29) Safer States. *PFAS.* https://www.saferstates.com/toxic-chemicals/pfas/ (accessed 2021−11−11).

(30) Washington State Department of Ecology. *Toxics in firefighting.* https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Addressing-priority-toxic-chemicals/PFAS/Toxics-in-firefighting (accessed 2022−01−12).

(31) Department of Defense. *Prohibition of Testing and Training with Fluorinated Aqueous Film Forming Foam*, 2020.

(32) Boeing. *Statistical Summary of Commercial Jet Airplane Accidents*, 2021.

(33) Gillespie, B.; Back, G. G.; Hughes, J.; Breed, B. *Foam Application for High Hazard Flammable Train (HHFT) Fires*; Fire Protection Research Foundation, 2017.

(34) Reade, A.; Yiliqi *New EPA Data: Huge Amounts of PFAS Underreported and Burned*; NRDC. https://www.nrdc.org/experts/yiliqi/new-epa-data-huge-amounts-pfas-underreported-and-burned-0 (accessed 2021−12−14).

(35) U.S. Census Bureau. North American Industry Classification System (NAICS). https://www.census.gov/naics/ (accessed 2021−11−11).

(36) Professional Environmental Engineers Inc.; Kansas Department of Health and Environment. *Final Statewide Inventory of Potential Perfluoroalkyl Substances (PFAS) Sites in Kansas*, 2019.

(37) Eastern Research Group. *PFAS Handling Industry Sectors*, 2019.

(38) Schulz, K.; Filbin, R.; Silva, M. R.; Klaper, R.; Boyer, T. Linking Industrial Point Sources to PFAS Contamination in Wells: Michigan Case Study. *Research Square*, June 28, 2021. https://www.researchsquare.com/article/rs-473338/v1.

(39) Association of State Drinking Water Administrators. *Per- and Polyfluoroalkyl Substances (PFAS) Source Water Protection Guidance Project: Technical Appendix*, 2020.

(40) Massachusetts Science Advisory Board. *Per- and Poly-Fluorinated Alkyl Substances (PFAS): Policy Analysis Toxics Use Reduction Institute*, 2021.

(41) Minnesota Pollution Control Agency. *Limited Phase I Inventory Assessment*, 2020.

(42) Utah Department of Environmental Quality. *Reconnaissance Plan for Per and Polyfluoroalkyl Substances (PFAS) in Utah*, 2020.

(43) U.S. EPA. *Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting*, 2019.

(44) U.S. EPA. *Addressing PFOA and PFOS in the Environment: Potential Future Regulation Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act*, 2021.

(45) Coggan, T. L.; Moodie, D.; Kolobaric, A.; Szabo, D.; Shimeta, J.; Crosbie, N. D.; Lee, E.; Fernandes, M.; Clarke, B. O. An Investigation into Per- and Polyfluoroalkyl Substances (PFAS) in Nineteen Australian Wastewater Treatment Plants (WWTPs). *Heliyon* **2019**, *5* (8), e02316.

(46) Maine Department of Environmental Protection. *Per- and Polyfluoroalkyl Substances (PFAS).* https://www.maine.gov/dep/spills/topics/pfas/ (accessed 2022−01−12).

(47) Liu, S.; Zhao, S.; Liang, Z.; Wang, F.; Sun, F.; Chen, D. Perfluoroalkyl Substances (PFASs) in Leachate, Fly Ash, and Bottom Ash from Waste Incineration Plants: Implications for the Environmental Release of PFAS. *Sci. Total Environ.* **2021**, *795*, 148468.

(48) Winchell, L. J.; Ross, J. J.; Wells, M. J. M.; Fonoll, X.; Norton, J. W., Jr; Bell, K. Y. Per- and Polyfluoroalkyl Substances Thermal Destruction at Water Resource Recovery Facilities: A State of the Science Review. *Water Environ. Res.* **2021**, *93* (6), 826−843.

(49) Ng, C.; Cousins, I. T.; DeWitt, J. C.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Patton, S.; Scheringer, M.; Trier, X.; Wang, Z. Addressing Urgent Questions for PFAS in the 21st Century. *Environ. Sci. Technol.* **2021**, *55* (19), 12755−12765.
(50) U.S. Army Corps of Engineers Geospatial. *Military Installations, Ranges, and Training Areas (MIRTA)*, 2021.
(51) U.S. Army Corps of Engineers Geospatial. *Formerly Used Defense Sites (FUDS), All Data, Reported to Congress in FY2019*, 2021.
(52) Federal Aviation Administration. *Air Carriers using Part 139 Airports*. https://www.faa.gov/airports/airport_safety/part139_cert/air-carriers-using-part-139-airports/ (accessed 2021−11−14).
(53) U.S. EPA. *Toxics Release Inventory (TRI) Program*. https://www.epa.gov/toxics-release-inventory-tri-program (accessed 2021−11−14).
(54) U.S. EPA. *Facility Registry Service (FRS)*. https://www.epa.gov/frs (accessed 2021−11−14).
(55) Ivahnenko, T. National USEPA Clean Watershed Needs Survey WWTP Nutrient Loads 1978 to 2012, 2017. https://www.sciencebase.gov/catalog/item/582f41a4e4b04d580bd51af5.
(56) MassDEP. *NPDES Permits: What You Need to Know | Mass.gov*. https://www.mass.gov/guides/npdes-permits-what-you-need-to-know (accessed 2022−01−12).
(57) *R: The R Project for Statistical Computing*. https://www.r-project.org/ (accessed 2022−07−14).
(58) RStudio Team. *RStudio: Integrated Development for R*; RStudio: Boston, MA, 2020.
(59) US Census Bureau. *Cartographic Boundary Files*. https://www.census.gov/geographies/mapping-files/time-series/geo/carto-boundary-file.html (accessed 2021−11−14).
(60) Pebesma, E.; Bivand, R.; Racine, E.; Sumner, M.; Cook, I.; Keitt, T.; Lovelace, R.; Wickham, H.; Ooms, J.; Müller, K.; Pedersen, T. L.; Baston, D.; Dunnington, D. *Sf: Simple Features for R*. 2021
(61) PFAS Project Lab; PFAS Exchange. PFAS Sites and Community Resources. https://experience.arcgis.com/experience/12412ab41b3141598e0bb48523a7c940/ (accessed 2022−01−12).
(62) Social Science Environmental Health Institute (SSEHRI). *PFAS Contamination Site Tracker*, 2021.
(63) Cui, D.; Li, X.; Quinete, N. Occurrence, Fate, Sources and Toxicity of PFAS: What We Know so Far in Florida and Major Gaps. *TrAC Trends Anal. Chem.* **2020**, *130*, 115976.
(64) *Per- and Polyfluoroalkyl Substances (PFAS)*; California State Water Resources Control Board. https://www.waterboards.ca.gov/pfas/ (accessed 2022−07−14).
(65) New York State Department of Environmental Conservation. *PFOA/PFOS Facility Identification Survey*, 2017.
(66) *Class B Fire Suppression Foam Usage Survey - New York State Airports*, 2017.
(67) *Class B Fire Suppression Foam Usage Survey - New York State Fire Training Centers*, 2017.
(68) U.S. EPA. *Fifth Unregulated Contaminant Monitoring Rule*. https://www.epa.gov/dwucmr/fifth-unregulated-contaminant-monitoring-rule (accessed 2021−11−14).
(69) U.S. Geological Survey. *Domestic (Private) Supply Wells*; 2019.
(70) Racicot, F.; Spidell, B. *Presumptive Coverage for Firefighters and Other First Responders*; National Council on Compensation Insurance, 2018.
(71) Palmer, M. G. The Legacy of Agent Orange: Empirical Evidence from Central Vietnam. *Soc. Sci. Med.* **2005**, *60* (5), 1061−1070.
(72) Casper, M. J. *Synthetic Planet: Chemical Politics and the Hazards of Modern Life*; Routledge: New York, 2003.
(73) Fassinger, M. E. Striking a Better Compromise: Suggested Revisions to the Agent Orange Act of 1991. *Fed Cir BJ.* **2011**, *21*, 193.
(74) U.S. Department of Veterans Affairs. *Agent Orange exposure and VA disability compensation*. https://www.va.gov/disability/eligibility/hazardous-materials-exposure/agent-orange/ (accessed 2021−12−13).

Appendix A

Legal Appendix to the Comments of the American Water Works Association on EPA's Proposal to Add Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) to the CERCLA List of Hazardous substances

LEGAL APPENDIX TO THE COMMENTS OF THE AMERICAN WATER WORKS ASSOCIATION ON EPA'S PROPOSAL TO ADD PERFLUOROOCTANOIC ACID (PFOA) AND PERFLUOROOCTANESULFONIC ACID (PFOS) TO THE CERCLA LIST OF HAZARDOUS SUBSTANCES

November 7, 2022

Susan Parker Bodine
Partner, Earth & Water Law
Former EPA Assistant Administrator, Office of Enforcement and Compliance Assurance
Former EPA Assistant Administrator, Office of Solid Waste and Emergency Response
Former Chief Counsel, Senate Committee on Environment & Public Works

parties who may have been inadvertently impacted by the contamination."[28] *This statement is not reassuring.* Even if EPA decides to forego suing a party inadvertently caught up in CERCLA liability, the reality is that only about a third of Superfund cases are filed by the federal government.[29] In EPA's nonbinding guidance to EPA regions on the exercise of enforcement discretion under CERCLA, it is telling that the vast majority of the cases cited in guidance involve private party plaintiffs.[30]

It is a common strategy for an industrial entity that is sued by EPA to file third-party contribution claims to bring as many small and municipal entities into a Superfund case as possible. For example, at the Operating Industries Superfund Site in California, the corporations targeted by EPA for the cleanup of this landfill sued 29 cities and towns, which over the course of three years spent *$7 million* on legal fees and technical experts.[31] The goal of these third-party plaintiffs is not only to spread costs, but also to gain leverage with EPA over cleanup costs.[32] Similarly, after entering into an agreement with EPA and New Jersey to carry out the remedial investigation at the Passaic River Superfund Site, the defendants filed a third-party

[28] *See supra* note 6. Hereinafter, this Legal Appendix adopts EPA's terminology and refers to these parties as "inadvertent parties."

[29] "Superfund Litigation Has Decreased and EPA Needs Better Information on Site Cleanup and Cost Issues to Estimate Future Program Funding Requirements," GAO-09-656 (July 2009), at 39, available at https://www.gao.gov/assets/gao-09-656.pdf and attached.

[30] *See, e.g.,* EPA, *Enforcement Discretion Guidance Regarding Statutory Criteria for Those Who May Qualify as CERCLA Bona Fide Prospective Purchasers, Contiguous Property Owners, or Innocent Landowners ("Common Elements")* (Jul. 29, 2019), available at https://www.epa.gov/sites/default/files/2019-08/documents/common-elements-guide-mem-2019.pdf and attached.

[31] *See* Steinzor, R and Kolker, D, "Superfund Liability dumped onto local governments," Government Finance Review, Aug. 1, 1993, available at https://www.thefreelibrary.com/Superfund+liability+dumped+onto+local+governments.-a014379911 and attached.

[32] *Id.*

savings to small entities resulting from a reduction in litigation costs resulting from a change to a definition.[90]

Finally, it is disingenuous for EPA to imply that creating CERCLA liability for PFOA and PFOS releases creates no new costs and instead simply transfers responsibility for current expenditures from the public to "polluters." According to EPA:

> An important outcome of the proposed rule is that with PFOA and PFOS designated as CERCLA hazardous substances, response costs are more likely to be borne by responsible parties. Cost transfers from the public to parties responsible for pollution are associated with the enhancement of EPA's existing authority under CERCLA 104(a) to recover costs incurred by the government for site-specific response actions.[91]

The reality is that (1) notwithstanding the authority to do so, EPA currently is not expending significant Superfund trust fund dollars on PFAS releases,[92] (2) EPA carries out only a fraction of hazardous substance response actions, and (3) expenditure of costs for PFOA and PFOS response actions are far more likely to be driven by third party claims, not EPA. Thus, the explosion in PFAS cleanup expenditures that would be driven by this proposed rule is *not part of the baseline* for analyzing costs.

A cursory glance at EPA's PFAS occurrence data makes it clear why this is true.[93] EPA reports PFAS detections at only 245 NPL sites, where it has authority to expend appropriated dollars for remedial actions.[94] In contrast, DOD has notified 2,143 agricultural operations that are

---

[90] 57 Fed. Reg. 18,344 (Apr. 29, 1992). The D.C. Circuit vacated this rule on other grounds but that vacatur does not diminish the fact that in 1992 EPA believed that liability costs should be considered when determining whether a Regulatory Impact Analysis is required.
[91] Economic Assessment, at 10.
[92] This could change given the reinstatement of the Superfund taxes, discussed *supra* note 19 and accompanying text.
[93] *See supra* note 82.
[94] *See* 40 C.F.R. 300.425(b)(1) ("Only those releases included on the NPL shall be considered eligible for Fund-financed remedial action."). EPA's list of NPL sites with PFAS is available at: https://echo.epa.gov/tools/data-downloads/national-pfas-datasets#identified

Superfund remedial actions, EPA will not have the authority to expend Superfund dollars in that state.[128]

EPA must analyze these impacts on hazardous waste infrastructure and on Superfund cleanups.

EPA's position that no RIA is needed is not consistent with agency precedent. In 1985, EPA prepared a full Regulatory Impact Analysis for its rulemaking adjusting the reportable quantities of the original list of CERCLA hazardous substances, even though that rule was not considered a "major rule."[129] Unlike the Economic Assessment for this economically significant rule, EPA's 253 page 1985 RIA included chapters on need and consequences, alternatives, effects (including induced response actions), costs (including costs of response by private parties and EPA), benefits, resource availability, firm and macroeconomic effects, and savings and a sensitivity analysis. This document belies EPA's claims that induced effects (like increased litigation and response costs) are neither relevant nor quantifiable.

IV. EPA Must Identify What Constitutes a Significant Danger and What Data Support EPA's Conclusion that PFOA and PFOS May Present a Significant Danger.

Section 102 of CERCLA gives EPA the authority to add to the list of hazardous substances after determining that a substance may present a substantial danger to the public health or welfare or the environment when released into the environment.[130] This authority is untested.

A. EPA's Interpretation of Section 102 of CERCLA is Flawed

In the NPRM, EPA proposes to interpret the phrase "may present" to mean that "Congress did not require certainty that the substance presents a substantial danger or require proof of actual

[128] 42 U.S.C. § 9604(c)(3)(B) and (c)(9).
[129] Regulatory Impact Analysis of Reportable Quantity Adjustments Under Sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act, Mar. 1985 (EPA-HQ-OLEM-2019-0341-0052).
[130] 42 U.S.C. § 9602(a).

harm."[131] Having said what is *not* required, nowhere does EPA articulate what *is* required. EPA never identifies the threshold of potential risk it believes is "substantial." Instead, EPA points to prior determinations that PFOA and PFOS may have "adverse" effects.[132] The data referenced to support a finding of "adverse" effects (not substantial danger) show "associations" between PFOA and PFOS and such effects.[133] EPA identifies these associations as the basis for its determination that PFOA and PFOS may present a substantial danger:

> In sum, studies have shown that exposure to PFOA and PFOS is associated with numerous and varied adverse effects to human health. This evidence plays a major role in the EPA's proposal to designate PFOA and PFOS as hazardous substances.[134]

Without identifying what threshold of risk it considers to present a significant danger, EPA combines potential adverse effects with mobility, persistence, and prevalence, to conclude that:

> The adverse human health effects, mobility, persistence, prevalence, and other factors related to these PFAS combine to support EPA's proposed finding that PFOA and PFOS, when released into the environment may present substantial danger to the public health or welfare or the environment and, as a result, warrant designation as CERCLA hazardous substances.[135]

This finding is devoid of content. EPA is saying that because a "substantial danger" need not be certain, then *any level of risk* is sufficient to support listing a chemical as a CERCLA hazardous substance as long as it also is mobile, persistent, and prevalent. This interpretation reads the "substantial danger" standard out of the statute and leaves EPA with no intelligible principle to apply when making a listing decision.

In fact, under EPA's interpretation of section 102, it could list dihydrogen monoxide as a CERCLA hazardous substance. Far from merely being "associated" with "adverse" effects, dihydrogen monoxide is known to cause death if you breathe it or ingest too much and the mechanism for

---

[131] 87 Fed. Reg. at 54,421.
[132] *Id.* at 54,424-26.
[133] *Id.* at 54,425,26.
[134] *Id.* at 54,426.
[135] *Id.* at 54,417.

these effects is well understood. Further dihydrogen monoxide is mobile, persistent, and prevalent. While it can be transformed, it can be neither created nor destroyed. Its chemical symbol is H_2O. It is, of course, water.

If EPA's statutory interpretation is correct, then section 102 of CERCLA is an unconstitutional delegation of legislative authority to EPA.[136] However, applying the statutory interpretation canon of "constitutional avoidance" no court would uphold EPA's interpretation.[137]

B. Alternative Interpretations of the Phrase "Substantial Danger"

Contrary to EPA's interpretation of section 102, the phrase "substantial danger" is not standardless. In fact, EPA has already given it meaning under CERCLA and has given meaning to similar language in RCRA. Examining those precedents, it is clear that the term "substantial danger" must be based on scientific evidence that significant harm could result if exposure occurs and the term "may present" must be based on plausible exposure scenarios arising from PFOA and PFOS releases to the environment.

The phrase "substantial danger" is used in the CERCLA definition of "remedy." A "remedy" is an action that addresses hazardous substances "so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment."[138] The phrase also is used in section 105 of CERCLA, where Congress directs EPA to revise the National Contingency Plant (NCP) to include "methods for evaluating, including analyses of

---

[136] *See, e.g., Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 472 (2001) (describing the nondelegation doctrine as a principle which prevents Congress from delegating its legislative powers to agencies unless Congress provides an "intelligible principle" to which the agency must conform).

[137] *See Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*, 531 U.S. 159, 173 (2001) (where a construction of a statute would raise serious constitutional problems the Supreme Court will construe the statute to avoid such problems).

[138] 42 U.S.C. § 9601(24).

ISRI
Voice of the Recycling Industry™

ISRI is the voice of the recycling industry, promoting safe, economically sustainable and environmentally responsible recycling through networking, advocacy and education.

Via electronic delivery at www.regulations.gov

November 7, 2022

U.S. Environmental Protection Agency
EPA Docket Center
OLEM Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; EPA–HQ–OLEM–2019–0341

Dear Ms. Schutz:

The Institute of Scrap Recycling Industries, Inc. (ISRI) is pleased to submit the following comments for consideration by EPA's Office of Land and Emergency Management in response to its proposed rule, "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances" (the Proposed Rule).[1]

ISRI is the *Voice of the Recycling Industry*®. With headquarters in Washington, DC and 18 chapters nationwide, ISRI represents more than 1,500 companies that process, broker, and consume recyclable materials, including metals, paper, plastics, glass, rubber, electronics, and textiles. ISRI provides education, advocacy, and safety and compliance training, and promotes public awareness of the essential role that recycling plays in the U.S. economy, global trade, the environment, and sustainable development. Generating nearly $117 billion annually in U.S. economic activity, the recycled materials industry supports more than 500,000 Americans with good jobs.

As detailed below in ISRI's comments on the Proposed Rule, EPA's emphasis on certain direct effects of the Proposed Rule downplays likely immediate significant other effects, including a substantial amount of litigation with significant attendant costs. The Proposed Rule significantly expands the universe of potentially responsible parties (PRPs) beyond those who produced or intentionally used PFOA or PFOS to almost anyone who owns land. Designation of PFOA and PFOS as CERCLA hazardous substances means that persons having nothing to do with producing or intentionally using PFOA or PFOS, including ISRI members, can be held liable for the cleanup of PFOA and PFOS contamination. Due to the foreseeable resulting litigation, the designations proposed by EPA will likely economically harm ISRI members and other persons not involved in the production or intentional use of PFOA or PFOS. EPA

[1] 87 Fed. Reg. 54415-54442, September 6, 2022.

1250 H St NW Suite 400, Washington, DC 20005 | (202) 662-8500 | isri@isri.org | ISRI.org

must address this potential economic harm when considering a final rule. Finally, the Proposed Rule is an "economically significant action" and a "major rule" because it will have an annual effect on the economy of $100 million or more. As a "major rule" under the Congressional Review Act, the Proposed Rule, if finalized, would be subject to the Act's Congressional disapproval procedure.

I. Background

ISRI takes great interest in the Proposed Rule because of its foreseeable consequences. As EPA noted, PFOA and PFOS have been used in many industrial, commercial and consumer products for decades. At end of life, some of these products may be received by recycling facilities as recyclable materials (input of recycling process) for processing into recycled materials (output of recycling process). From a recycling perspective, PFOA and PFOS are incidental to any recyclable material and do not provide any value to recycling processes, recyclable material, and recycled materials; that is, there is no intention to recycle PFOA or PFOS. The recycled materials industry does not intentionally use PFOA or PFOS in its recycling processes. This situation is the same as that of wastewater treatment plants (WWTPs), in that WWTPs incidentally receive PFOA and PFOS as part of WWTP influent from households, commercial establishments, and other wastewater dischargers. Nonetheless, the possibility exists that PFOA or PFOS is present at recycling facilities, whether from certain recyclable materials received over time, any firefighting activities using aqueous film-forming foam including on-site firefighting training offered to local fire departments, or off-site environmental sources such as precipitation.[2] This possibility makes the Proposed Rule relevant to the recycled materials industry.

As EPA notes, "CERCLA was enacted to promote the timely cleanup of contaminated sites and to ensure that parties responsible for the contamination bear the costs of such cleanups".[3] However, the historical context of CERCLA generally concerned a contaminated site with a finite extent of contamination (even if large in area, multi-contaminant, and multimedia) involving a finite set of PRPs (even if numerous). PFOA and PFOS challenge the assumptions of CERCLA because "PFOA and PFOS are common contaminants in the environment because of their release into the environment since the 1940s and their resistance to degradation".[4] Given their nationwide presence in the environment, if PFOA and PFOS become CERCLA hazardous substances, the scope of PRP expands well beyond parties who produced or intentionally used PFOA or PFOS to include anyone who unintentionally handles PFOA or PFOS with some of it becoming "located" at the "facility".[5] EPA does not acknowledge this expanded scope of PRP and its foreseeable consequences in the Proposed Rule.

---

[2] Pike, K.A.; Edmiston, P.L.; Morrison, J.J.; and Faust, J.A. Correlation analysis of perfluoroalkyl substances in regional U.S. precipitation events. *Water Res.* **2021**, *190*, 116685. https://doi.org/10.1016/j.watres.2020.116685.
[3] Proposed Rule 54420.
[4] Id. 54426.
[5] See CERCLA Section 101(9).

II. Comments

From ISRI's perspective, EPA takes a limited view of the consequences of designating PFOA and PFOS as CERCLA hazardous substances under CERCLA Section 102(a). EPA emphasizes the "direct" effects of the Proposed Rule and effectively discounts its other immediate, if not direct, effects. As a result, EPA significantly downplays the foreseeable consequences and costs of the Proposed Rule.

A. EPA's Emphasis on Certain Direct Effects of the Proposed Rule Downplays Likely Immediate Significant Other Effects, Including Substantial Amounts of Litigation.

EPA's emphasis on certain direct effects of the Proposed Rule downplays likely immediate significant other effects. In the preamble of the Proposed Rule, EPA identifies only three direct effects of the proposed designation, besides the default setting of their reportable quantity (RQ) at 1 pound each under Section 102(b): (1) reporting and notification obligations for releases pursuant to Section 103; (2) notification by Federal agencies when selling or transferring any Federally-owned real property pursuant to Section 120(h); and (3) listing and regulation as hazardous materials by DOT pursuant to Section 306(a). In the case of (1), reporting and notification for a release of a RQ or more of a CERCLA hazardous substance from a facility to off-site within a 24-hour period (with some exceptions) are required separately by CERCLA regulation at 40 CFR §302.6 to the National Response Center and by Emergency Planning and Community Right-to-Know Act (EPCRA) regulation at 40 CFR §355.30 to the State (or Tribal) Emergency Response Commission and Local (or Tribal) Emergency Planning Committee (or 911/operator during transport).

In ISRI's view, designation of PFOA and PFOS as CERCLA hazardous substances has much broader immediate (if not direct) effects than just EPA's three cited direct effects. These broader direct effects arise from several definitions and Sections 107 and 113 under CERCLA. The relevant CERCLA definitions in Section 101 are "facility", "onshore facility", "owner or operator", and "person" (in pertinent part):

(9) The term "facility" means…(B) any site or area where a hazardous substance has been deposited, stored, disposed of, or placed, or otherwise come to be located….

(18) The term "onshore facility" means any facility (including, but not limited to, motor vehicles and rolling stock) of any kind located in, on, or under, any land or nonnavigable waters within the United States.

(20)
(A) The term "owner or operator" means…(ii) in the case of an onshore facility or an offshore facility, any person owning or operating such facility,…

(21) The term "person" means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, or any interstate body.

With respect to "person", any individual (human being) is a CERCLA "person".

With respect to "facility", the information provided by EPA in the preamble of the Proposed Rule suggests that PFOA and PFOS are present throughout the U.S. in outdoor air, surface water, drinking water, and surface and subsurface soils.[6] In fact, EPA specifically states that "this information illustrates the prevalence of PFOA and PFOS in water, soil, air, plants, and animals worldwide due to its transportability and persistence." New research provides additional evidence of the nationwide presence of PFAS generally, if not PFOA and PFOS specifically, including presumptively (and conservatively) at more than 57,000 U.S. facilities.[7] The significance of this likely nationwide presence of PFOA and PFOS is that every square foot of U.S land is arguably part of a CERCLA "facility" and a CERCLA "onshore facility" because PFOA or PFOS "has…otherwise come to be located" there, if not "deposited, stored, disposed of, or placed" there.

With respect to "owner or operator", any individual that owns property (i.e., an onshore facility), where arguably PFOA or PFOS "has…otherwise come to be located"—if not "deposited, stored, disposed of, or placed" there—is a CERCLA "owner or operator".

Section 107(a) states that "(1) the owner…of…a facility" is a covered person who "(4)…shall be liable for–":

> *(A) all costs of removal or remedial action incurred by the United States Government or a State or an Indian tribe not inconsistent with the national contingency plan;*
>
> *(B) any other necessary costs of response incurred by any other person consistent with the national contingency plan;*
>
> *(C) damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such a release; and*
>
> *(D) the costs of any health assessment or health effects study carried out under section 9604(i) of this title.*

Section 113(f)(1) states:

> *Any person may seek contribution from any other person who is liable or potentially liable under section 9607(a) of this title, during or following any civil action under section 9606 of this title or under section 9607(a) of this title.*

---

[6] Proposed Rule 54426-54429.

[7] Salvatore, D.; Mok, K.; Garrett, K.K.; Poudrier, G.; Brown, P.; Birnbaum, L.S.; Goldenman, G.; Miller, M.F.; Patton, S.; Poehlein, M.; Varshavsky, J.; and Cordner, A. Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources. *Environ. Sci. Technol. Lett.* **2022**, XXXX, XXX, XXX-XXX. www.doi.org/10.1021/acs.estlett.2c00502.

When the above CERCLA definitions and provisions are taken together in the context of PFOA and PFOS, the Proposed Rule has the direct effect of making just about any owner of property, whether of industrial facilities or residential homes, a "covered person" with potential or actual CERCLA liability.

While these direct effects may also be true for any CERCLA hazardous substance (to the extent that only one molecule or atom of it is required), PFOA and PFOS are significantly different than current CERCLA hazardous substances because of their broad historical use and their hazard profiles. These differences matter. In a recent *Federal* Register notice,[8] EPA released interim lifetime drinking water health advisories of 0.004 parts per trillion (ppt) for PFOA and 0.02 ppt for PFOS and noted their carcinogenic potentials. These interim health advisories were "based on data and draft analyses that indicate that the levels at which negative health effects could occur are much lower than previously understood when the agency issued its 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt)".[9] They are below the analytical detection limits for PFOA and PFOS, respectively, in drinking water,[10] also noted by EPA.[11] These health advisories suggest that there is no safe non-zero concentration of PFOA and PFOS. Given the expected presence of PFOA and PFOS everywhere, there arguably is no place in the U.S. "safe" from PFOA and PFOS. While EPA notes that "[the health advisories] are not regulations and should not be construed as legally enforceable Federal standards,"[12] they do shape public perception and almost certainly influence people's (including organizations') behavior.

Based on the above, an expected immediate (if not direct) effect of the Proposed Rule is substantial amounts of litigation by private parties under Sections 107 and 113 with significant attendant costs. While "[CERCLA] confers considerable discretion upon the EPA in its exercise of [its response authorities]",[13] discretion by EPA is not controlling. EPA notes that "designating PFOA and PFOS as hazardous substances will…allow the government **<u>and private parties</u>** to seek to recover cleanup costs from potentially responsible parties assuming relevant statutory criteria are met" (emphasis added).[14] Litigation by private parties that invoke Sections 107 and 113 has happened in connection with other CERCLA hazardous substances without any action by EPA.[15] There is no reason to expect different behavior in the aftermath of these CERCLA designations under the Proposed Rule.

To the extent that designation of a substance as a CERCLA hazardous substance is intended to "signal to the market that there is value in the prevention of releases due to the burden in

[8] 87 Fed. Reg. 36848-49, June 21, 2022.
[9] Id. 36849.
[10] 0.53 ppt PFOA and 1.1 ppt PFOS in Table 5 of Method 537.1 (EPA Document #: EPA/600/R-20/006).
[11] Proposed Rule 54430.
[12] 87 Fed. Reg. 36848.
[13] Proposed Rule 54420.
[14] Ibid.
[15] See *Garrison Southfield Park LLC v. Closed Loop Refining and Recovery, Inc.*, 2019 BL 436160, S.D. Ohio, No. 17-cv-783, 11/13/19.

reporting",[16] as well as the burden of future cleanup costs, the Proposed Rule would not have that effect. PFOA and PFOS are already present nationwide at concentrations already deemed not "safe". The Proposed Rule does not seem likely to offer much prevention. However, the Proposed Rule does significantly expand the universe of PRPs beyond those who produced or intentionally used PFOA or PFOS to almost anyone who owns land. Designation of PFOA and PFOS as CERCLA hazardous substances means that persons having nothing to do with producing or intentionally using PFOA or PFOS, including ISRI members, can be held liable for the cleanup of PFOA and PFOS contamination. Due to the foreseeable resulting litigation, the designations proposed by EPA will likely economically harm ISRI members and other persons not involved in the production or intentional use of PFOA or PFOS. EPA must address this potential economic harm when considering a final rule.

B. The Proposed Rule is an "Economically Significant Action" and a "Major Rule" Because It Will Have an Annual Effect on the Economy of $100 Million or More.

In ISRI's view, the Proposed Rule is an "economically significant action" and a "major rule". The Proposed Rule would have an annual effect on the economy of $100 million or more. While EPA considers the Proposed Rule to be a "significant regulatory action", EPA should have found that it would also have a significant monetary impact on the economy.

EPA states:[17]

> *This action is a significant regulatory action that was submitted to the OMB for review. While EPA is not considering costs in its hazardous substance designation decisions in this proposed rule, and despite that there is still significant uncertainty and lack of data as discussed in the economic analysis (EA), OMB designated this proposed rulemaking as an economically significant action.*

In its assessment of costs and other impacts of the Proposed Rule, EPA classifies the Proposed Rule as a "significant regulatory action" because the "action may raise novel legal or policy issues arising out of legal mandates, the Presidents' priorities, or the principles set forth in the [Executive Order (EO) 12866]."[18] This is the fourth of four alternative criteria for a "significant regulatory action" in EO 12866. EPA does not base this classification on the first criterion:[19]

> *Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;*

[16] "Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as Hazardous Substances" (EPA-HQ-OLEM-2019-0341-0034) 4.
[17] Proposed Rule 54439.
[18] "Economic Assessment" (Footnote 16) 52.
[19] Executive Order 12866 of September 30, 1993 (58 Fed. Reg. 51735).

EPA opts for "novel legal or policy issues" over "annual effect on the economy of $100 million or more" because it did not consider costs in its designation of PFOA and PFOS as CERCLA hazardous substances and considered assessing "indirect" response costs to be "impractical" due to "uncertainty".[20] In invoking impracticality and uncertainty, EPA effectively assigns a value of $0 to "indirect" response costs arising from the Proposed Rule. A value of $0 is certainly incorrect. An Office of Management and Budget (OMB) document provides an understanding of the $100 million threshold in the first criterion (emphasis original):[21]

> *The $100 million threshold applies to the impact of the proposed or final regulation in* any one year*, and it includes* benefits, costs, or transfers*. (The word "or" is important: $100 million in annual benefits, or costs, or transfers is sufficient; $50 million in benefits and $49 million in costs, for example, is not.)*

Given the evidence of the nationwide presence of PFOA and PFOS and their hazard profiles, it is not difficult to imagine that designation of PFOA and PFOS as CERCLA hazardous substances would result in $100 million in "benefits, costs, **or** transfers" in any future year (even the first year) due to litigation and other actions. New research estimates conservatively that more 57,000 sites in the U.S. have presumptive PFAS contamination.[22] Assuming that this conservative (i.e., low) count is equally offset by the possibility that not all of these sites necessarily have PFOA or PFOS contamination, assigning an annual cost of $2,000 to each facility as a consequence of the proposed designations would put the annual cost above $100 million. This makes the Proposed Rule an "economically significant rule". This scenario does not even envision the costs of likely substantial litigation under the Proposed Rule, so an annual amount may be much greater.

As an "economically significant rule" based on the $100 million threshold, the Proposed Rule also qualifies as a "major rule" under the Congressional Review Act (CRA) for having "an annual effect on the economy of $100,000,000 or more".[23] As a "major rule" under the CRA, the Proposed Rule, if finalized, would be subject to the Congressional disapproval procedure of the CRA.[24]

---

[20] Proposed Rule 54423.
[21] Regulatory Impact Analysis: Frequently Asked Questions (FAQs), February 7, 2011 (OMB Circular A-4 FAQ) (EPA-HQ-OLEM-2019-0341-0203).
[22] Salvatore, D.; Mok, K.; Garrett, K.K.; Poudrier, G.; Brown, P.; Birnbaum, L.S.; Goldenman, G.; Miller, M.F.; Patton, S.; Poehlein, M.; Varshavsky, J.; and Cordner, A. Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources. *Environ. Sci. Technol. Lett.* **2022**, XXXX, XXX, XXX-XXX. www.doi.org/10.1021/acs.estlett.2c00502.
[23] 5 U.S.C. §804(2)(A).
[24] 5 U.S.C. §802.

III. Summary

ISRI finds that EPA's emphasis on certain direct effects of the Proposed Rule downplays likely immediate significant other effects, including a substantial amount of foreseeable litigation with significant attendant costs. The Proposed Rule significantly expands the universe of PRPs beyond those who produced or intentionally used PFOA or PFOS to almost anyone who owns land. Designation of PFOA and PFOS as CERCLA hazardous substances means that persons having nothing to do with producing or intentionally using PFOA or PFOS, including ISRI members, can be held liable for the cleanup of PFOA and PFOS contamination. Due to the foreseeable resulting litigation, the designations proposed by EPA will likely economically harm ISRI members and other persons not involved in the production or intentional use of PFOA or PFOS. EPA must address this potential economic harm when considering a final rule. Finally, the Proposed Rule is an "economically significant action" and a "major rule" because it will have an annual effect on the economy of $100 million or more. As a "major rule" under the CRA, the Proposed Rule, if finalized, would be subject to the Congressional disapproval procedure of the CRA.

In closing, ISRI appreciates this opportunity to provide comment on the proposed rule, "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances", and EPA's consideration of these comments. If you have any questions, you can reach me at DWagger@isri.org or 202-662-8533.

Sincerely,

David L. Wagger

David L. Wagger, Ph.D.
Chief Scientist / Director of Environmental Management
Institute of Scrap Recycling Industries, Inc.

Comments of the U.S. Chamber of Commerce
Coalition of Companies and Trade Associations on

Proposed Rule, Environmental Protection Agency; Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances; 87 Fed. Reg. 54,415 (Sept. 6, 2022), Docket ID No. EPA–HQ–OLEM–2019-0341(pp. 54415-54442)

Submitted on regulations.gov

November 7, 2022

I. Introduction

The U.S. Chamber of Commerce Coalition of Companies and Trade Associations (the Coalition) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA's) precedent-setting proposed rule[1] in which EPA proposes to define and exercise its authority for the first time under Section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), also known as the Superfund statute, to designate the following substances as "hazardous substances:" perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), including their salts and structural isomers (hereinafter referred to as the "proposed rule" or "proposal"). This proposed rule is part of EPA's overall whole-of-government approach to addressing per- and polyfluoroalkyl substances (PFAS) as outlined in its 2021-2024 PFAS Strategic Roadmap.[2]

The Coalition represents downstream product manufacturers and users of PFOA and/or PFOS products, previous manufacturers and processors, and businesses in other areas of the value chain across the broad economy potentially impacted by the proposal.[3] The Coalition is composed of a wide cross-section of trade associations and industries, including aerospace, automotive, construction, electronics, energy, mining, health care, telecommunications, and textiles, and other community stakeholders, including first responder services, water and wastewater utilities, and waste management facilities. The Coalition also represents other businesses who could potentially be subject to CERCLA liability for PFOA and PFOS. The U.S. Chamber of Commerce is the largest business trade association in the world, representing more than 3 million companies of all sizes and sectors.

While EPA, in proposing the rule, has attempted to evaluate the potential impacts of the proposal, it has fallen short in this task. Among other things, EPA has failed altogether to assess the larger legal, economic, operational, and practical consequences looming from the proposed rule—that CERCLA's strict liability and cost recovery scheme would apply to potentially responsible businesses and landowners, including public entities, for any site in the country containing any level of PFOA and PFOS, which are some of the most pervasive contaminants known today.

The Coalition identified significant uncertainties[4] related to the proposal that would make implementation of, let alone commenting on, this proposed rule challenging.

EPA has ample existing authority to protect the public health, welfare, and the environment from potential risks posed by legacy PFOA and PFOS under current law, yet it has proposed to expand the use of CERCLA as an ill-suited regulatory tool to address challenges presented by PFOA and PFOS. This proposed reliance on EPA's CERCLA authorities is unlikely to accomplish EPA's stated goal of reducing exposures to PFOA and PFOS and

---

[1] 87 Fed. Reg. 54,415 (Sept. 6, 2022).
[2] EPA, PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024, https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024.
[3] Throughout these comments, when we refer to PFOA and PFOS, all references are meant to also include all their salts and their branched and linear structural isomers. This is consistent with EPA's approach in the proposed rule.
[4] *See* U.S. Chamber Coalition letter to Michael. S. Regan, EPA Administrator (Oct. 18, 2022) submitted to regulations.gov docket EPA–HQ–OLEM–2019-0341 (Nov. 7, 2002) tracking number la6-wbef-8e82.

enforceable drinking water standards for PFOA and PFOS under the Safe Drinking Water Act.[68] EPA should finalize or revise this guidance according to the statutory deadlines before moving forward with this proposal. These interim proposals create significant regulatory uncertainty as to how EPA will set cleanup target levels at contaminated sites, particularly because the levels being contemplated are below the level of detection.

Until the science is improved, and applicable regulatory levels are finalized, stakeholders should not be required to guess at the range of potential levels of PFOA and PFOS that will be subject to assessment and remediation. EPA must complete a full RIA that incorporates reasonable assumptions for cleanup target levels, which is essential to understanding the true, direct, and foreseeable costs and impacts of this proposal.

Ultimately, this proposed rule and EPA's interim health advisories raise the specter of forcing site cleanup to levels beyond the detection ability of modern laboratory methods. This is a significant aspect of the problem of using CERCLA to address PFOA and PFOS that is not addressed by the proposed rule. In short, the normal CERCLA site assessment and remediation process does not provide the capacity to address the extraordinarily low levels of PFOA and PFOS that EPA has identified in the health advisories. If EPA has any persuasive rationale to the contrary, it must explain that in this rulemaking, not only to demonstrate that EPA understands the consequences of this action, but also to ensure that EPA's decision is rational and to comply with notice and comment requirements. Moreover, the Chamber also modeled the proposed treatment costs at various cleanup levels, including 4 ppt, and found that the closer levels are to zero, the costs rise significantly.

5. The Listing Would Put Essential "Passive Receiver" Sectors at Risk

Listing PFOA and PFOS as CERCLA hazardous substances would substantiate the fears and concerns of essential "passive receiver" sectors that neither manufacture nor use PFOA or PFOS, including the drinking water, wastewater utility, and solid waste sectors. These sectors provide essential public services to communities across the United States. Unfortunately, a hazardous substance designation would result in increased costs for these sectors by driving their customers, ratepayers, and stakeholders into an endless spiral of increasing costs and liability, at a particularly inopportune time of drought and water scarcity for a large part of the nation.

Although technologies for removing PFAS in liquids is still developing, the most common treatment method for removing PFOA and PFOS is filtration through granular activated carbon (GAC), which can be regenerated by releasing captured contaminants using thermal reactivation. Similarly, industrial-scale reverse osmosis/nanofiltration (RO) has been used effectively to remove PFOA and PFOS. However, even RO is only 90 percent effective[69], which does not eliminate all risk. With PFOA and PFOS being designated as CERCLA hazardous substances, concerns about aerial releases of PFOA and PFOS during the reactivation process

---

[68] This rulemaking is pending before OMB.
[69] *See* EPA website, Reducing PFAS in drinking water with treatment technologies, (Aug. 23, 2018). Available at https://www.epa.gov/sciencematters/reducing-pfas-drinking-water-treatment-technologies.

may lead to greater reliance on landfills to manage GAC, RO, and other media contaminated with PFOA and PFOS.

PWSs are already on the front lines dealing with PFOA and PFOS. Faced with public pressure to meet EPA's 70 ppt PFOA and PFOS health advisory from 2016, many PWSs spent millions of dollars to meet this unenforceable standard by installing treatment equipment that was recently rendered inadequate when EPA issued its interim PFOA and PFOS health advisories that moved the goalposts more than 1,000-fold lower than the current advisory level.

Wastewater utilities could face even greater threats of CERCLA liability if PFOA and PFOS are designated as CERCLA "hazardous substances." CERCLA provides limited exemptions for publicly owned treatment works (POTWs), which can become subject to liability under CERCLA if a hazardous substance is introduced into the sewer systems from industrial and sometimes residential customers. Although industrial inputs are generally required to have permits for any discharges to POTWs, such permits may not cover or account for unregulated contaminants like PFOA and PFOS. CERCLA provides limited exemptions for POTWs that dealt with hazardous substances sent to them by others before they were declared CERCLA hazardous substances (or perhaps before CERCLA itself was enacted). Municipalities in these circumstances may find themselves trapped for years in litigation, in which PRPs seek to work out how much each party owes for cleanup costs.

EPA's designation of PFOA and PFOS as hazardous substances under CERCLA also would have significant cost impacts on the solid waste sector, as well as broad unintended consequences on Administration priorities. Although EPA has recognized landfilling as one of the few effective options for managing and limiting PFAS in the environment,[70] this rulemaking would force the waste sector to reject certain waste streams containing PFOA and PFOS while increasing disposal costs for many wastes.

Landfills that rely on wastewater treatment plants for their discharge would need to undertake leachate pretreatment, significantly adding to the costs of landfill operation. The estimated capital cost to implement leachate pretreatment and PFAS treatment at a moderate-sized landfill (i.e., biological treatment of 30,000-40,000 gallons per day of leachate) to the extent necessary to minimize PFAS in leachate ranges from $2 million to $12 million, or potentially far more.[71] Included in this cost estimate is approximately $0.5 million to $1.5 million for PFAS removal technology, with additional costs anticipated for landfills where more stringent effluent levels are desired or mandated (e.g., Michigan). This does not include costs for PFAS residuals management, which is currently less well understood because most technologies have not been evaluated at full-scale. The combined *increased costs associated with PFAS management thus could total approximately $966 million to $8.187 billion per year for*

[70] See EPA, *Interim Guidance on the Destruction and Disposal of PFAS and Materials Containing PFAS* (Dec. 18, 2020), https://www.epa.gov/system/files/documents/2021-11/epa-hq-olem-2020-0527-0002_content.pdf.
[71] The standards that would govern a PFOA or PFOS cleanup action currently are unclear, complicated by a patchwork of state regulatory standards and EPA's interim drinking water health advisories for PFOA and PFOS. As such, the costs of PFAS treatment borne by landfills and their customers could far exceed these estimates.

municipal solid waste landfills alone. These costs typically cannot be absorbed by local governments with municipally operated landfills.

The resulting increased costs could curtail the ability of some facilities to continue operating, resulting in limited options for the long-term management of spent filters from PWSs and POTWs as well as impacted soils at DoD facilities. Moreover, because states have been restricting the availability of incineration and land application as viable disposal outlets, any impact to the landfilling of these materials could accelerate the looming challenges for biosolids management in the United States.[72] Customers and ratepayers ultimately would bear the burden of these cost increases, potentially resulting in disproportionate impacts on low-income households that rely on the affordability of services provided by the solid waste sector, leading to a "community pays" model of CERCLA, contradictory to the "polluter pays" structure that Congress originally intended.

Thus, designation of PFOA and PFOS as CERCLA hazardous substances could create significant challenges for passive receivers, the most obvious one being increased costs associated with handling wastes that contain PFOA and PFOS.

6. EPA Has Failed to Explain Why it Cannot Use its Existing Authority to Accomplish EPA's and Industries' Common Goal to Clean Up Sites

One of the key reasons why EPA has failed to establish the requisite need to designate PFOA and PFOS as CERCLA hazardous substances is that it has failed to explain why it cannot use its existing authority to adequately effectuate cleanups.

First of all, EPA has failed to explain why it could not take action under the less onerous standard of treating PFOA and PFOS as CERCLA "pollutants or contaminants."[73] EPA asserts that "CERCLA already provides significant authority to federal agencies to address PFOA and PFOS releases because these two chemicals are pollutants and contaminants."[74] CERCLA authorizes EPA cleanup of CERCLA "pollutants or contaminants," and EPA has used that authority to require their cleanup.

Before declaring PFOA and PFOS to be "hazardous substances" pursuant to CERCLA Section 102(a), EPA should establish whether they qualify as CERCLA "pollutants or contaminants" and, if so, should utilize the ample tools available in the statute to address them as such, such as CERCLA removal authority, for when "there is a release or substantial threat of

---

[72] Maine, H.P. 1417 - L.D. 1911; Illinois, HB 3190; New York State, A10081.

[73] "The term 'pollutant or contaminant' shall include, but not be limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring." 42 U.S.C. § 9601(33).

[74] 87 Fed. Reg. at 54,420; *see also* 87 Fed. Reg. at 54,436 n.192 ("Where PFAS are commingled with CERCLA hazardous substances, EPA can require PRPs to address the PFAS. Additionally, CERCLA Section 120 federal facility agreements for federal facilities listed on the NPL require federal agencies to investigate and clean up hazardous substances, pollutants and contaminants which includes PFAS.").

d. U.S. Department of Defense Responsibilities

As part of the NDAA for Fiscal Year 2021, Congress imposed several requirements and obligations on the DoD regarding PFOA and PFOS. For example, Section 335 required DoD to publicly disclose the results of any testing for PFOA, PFOS, and other PFAS conducted on military installations or formerly used defense sites, regardless of whether the testing was conducted by DoD, federal agencies, or any other public or private entities. Section 332 required the DoD, when conducting removal or remedial actions pursuant to CERCLA or the NDAA for Fiscal Year 2020 of PFOA and/or PFOS contamination from DoD or National Guard activities found in drinking water, or in groundwater that is not currently used for drinking water, to ensure that these actions result in PFOA and PFOS levels that meet or exceed the most stringent of any enforceable state and federal drinking, surface, or groundwater standards or health advisories issued pursuant to SDWA Section 1412(b)(1)(F).[99]

B. A Listing Under CERCLA Section 102(a) Would Have Significant Unintended Consequences

1. The Listing Would Slow Down, Not Speed Up, Site Cleanups

EPA asserts that "[d]esignating PFOA and PFOS as hazardous substances may have indirect, indeterminate impacts associated with potential increases in the speed of response activity and in the total number of response actions taken to address PFOA and PFOS releases."[100] Remediating Superfund sites is a multi-year, if not multi-decade, process (involving site assessment, remedial investigation and feasibility study, remedy decisions, remedial design and remedial action, post-construction, and more). PRPs that do not agree to comply must be compelled by further litigation, which can also take many years. The process of allocating responsibility among PRPs can be time-consuming, with delays in figuring out the allocation of financial responsibility among the PRPs. Contrary to EPA's position, this entire process takes time and will, in fact, slow down the site cleanup process.

The data on the lack of progress EPA has made in its cleanup of Superfund sites demonstrate that the program is already lagging. For example, at the end of FY 2019, only 424 of the 1,757 sites that had been added to the NPL since 1980 have been deleted, meaning that all cleanup goals at these sites were achieved.[101] In reviewing the NPL list as of August 17, 2022, there are 329 sites.[102] Approximately 75 percent of the NPL is more than 20 years old.

Additionally, discovery of PFOA and PFOS contamination during the five-year reviews of facilities where CERCLA remediation was previously completed would clearly slow down the rate of sites deemed remediated and "closed." Even sites that underwent cleanup of groundwater contaminated with PFOA and/or PFOS to EPA's previous health advisory of 70 ppt would face

---

[99] NDAA FY2021 Section 332(c) is a "savings clause" that expressly states that the section does not affect the application of CERCLA in general, which would presumably include EPA's discretion to establish ARARs pursuant to CERCLA Section 121.
[100] 87 Fed. Reg. at 54,439.
[101] *See* https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0216.
[102] *See* https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0213.

risk that prior remedial efforts would not comply with future MCLs or MCLGs for PFOA and PFOS. Allowing EPA's remedial efforts to be driven by the presence of PFOA and PFOS may needlessly shift the focus away from the sites that pose the greatest risks to public health, welfare, and the environment and the sites where targeted cleanups may provide the greatest results, particularly without clear technical guidance on the identification of relevant PFOA/PFOS contamination sources, evaluation of background concentrations, and analytical methods for all environmental media.

In addition to causing government enforcement actions, a hazardous substance designation for PFOA and PFOS would likely spawn a significant rise in disruptive private-party CERCLA litigation. Under Section 113 of CERCLA, there are multiple circumstances where CERCLA contribution rights are triggered for private parties, based on certain legal actions and administrative and judicial settlements.[103] Additionally, cost recovery for voluntary cleanups is also available to private parties under Section 107 of CERCLA.[104] Coupled with CERCLA's extraordinarily broad liability structure, these private rights of action encourage litigation. Private CERCLA claims are not legally bound by any EPA enforcement guidance that could be crafted to try to blunt the unfairness of CERCLA's expansive liability structure.

For example, CERCLA litigation in New Jersey involving cleanup of hazardous substances in the Passaic River resulted in a settlement with industrial parties. Those parties then brought contribution actions against 261 third-party defendants, including 70 municipalities and other public entities, contending they bore site cleanup responsibility, resulting in litigation spanning eight years and culminating in a second settlement of $35.4 million.

Moreover, at sites that are the subject of private party litigation, EPA may be unwilling or unable to dedicate the necessary resources to attempt to negotiate settlements providing small contributors with contribution protection from other PRPs. Previous allocation litigation will not have included facts related to the contribution of PFOA or PFOS. These entirely different "waste" (or product manufacturing) streams that could not have been present in past negotiations would now need to be researched and considered, which could vastly change the CERCLA contribution allocation landscape, particularly for complicated multi-party sites like landfills. In any event, EPA cannot force such re-evaluations or settlements.

2. The Listing Would Affect Every Real Estate Transaction for Properties Where PFOA and PFOS Are Potentially Present

Designating PFOA and PFOS as hazardous substances under CERCLA Section 102(a) would likely cause the inventory of so-called "brownfield" sites to increase, given the widespread anthropogenic use of these chemicals in hundreds of consumer products and processes. In 2002, Congress sought to deal with a backlog of properties across the country, the "reuse of which may be complicated by the presence or potential presence of a hazardous substance, pollutant, or contaminant."[105] The purpose of this "Brownfield Program" was to facilitate property transactions that private parties, banks, and other financial institutions might

---

[103] 42 U.S.C. § 9613(f)(1) and (3)(B).
[104] *See U.S. v. Atlantic Research Corp.*, 551 U.S. 128 (2007).
[105] 42 U.S.C. § 9601(39).

refuse to participate in due to fears of assuming liability for cleaning up hazardous substances, especially where EPA's limited resources precluded assessing each property and releasing it from CERCLA jurisdiction. Congress created the "de minimis" settlement authority and "de micromis" exemption to facilitate this process, but qualifying for these protections involves satisfying complicated, stringent requirements. Thus, these tools are likely inadequate to address the broad concerns over PFOA and PFOS sites.

The widespread presence of PFOA and PFOS in the United States may present significant and potentially insurmountable challenges for anyone attempting to qualify for CERCLA's limited exemptions, exclusions, and defenses.[106] Many purchasers of property would at least have reason to know that the property was or could be contaminated with PFOA and PFOS. If this is taken to the extreme, it would preclude anyone from qualifying for the protections that Congress added to limit the potential for needless CERCLA liability for small parties. EPA's designation of PFOA and PFOS as hazardous substances pursuant to CERCLA Section 102(a) could unnecessarily complicate these issues.

3. There Will Likely Be a Lack of Adequate Disposal Capacity Nationwide

According to CERCLA Section 104(c)(9)(A), EPA cannot require remedial actions for either CERCLA "pollutants or contaminants" or "hazardous substances" unless certain conditions are met:

> unless the State in which the release occurs first enters into a contract or cooperative agreement with the President providing assurances deemed adequate by the President that the State will assure the availability of hazardous waste treatment or disposal facilities which… have adequate capacity for the destruction, treatment, or secure disposition of all hazardous wastes that are reasonably expected to be generated within the State during the 20-year period following the date of such contract or cooperative agreement and to be disposed of, treated, or destroyed….

As discussed, EPA has announced that it intends to designate PFOA and PFOS as RCRA hazardous constituents. The potential of CERCLA liability is pushing waste management facilities to reject receipt of non-hazardous waste PFOA/PFOS-containing materials and manage these only as RCRA hazardous wastes. EPA's justification for designating PFOA and PFOS as CERCLA hazardous substances fails to address whether states have adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in the next 20

[106] For example, regarding the de micromis exemption, the person must have transported or arranged for the disposal of some of the hazardous substance at a given facility on the National Priorities List before April 1, 2001. *See* 42 U.S.C. § 9607(o)(1)(B). Regarding the contiguous properties exemption, the person cannot have caused, contributed to, or consented to the disposal of the hazardous substances on the person's property and is not potentially liable for response costs at another facility. *See* 42 U.S.C. § 9607(q)(1)(A)(i), (ii)(I). Regarding the bona fide prospective purchaser exemption, the person must prove that no disposal of hazard substances at the facility occurred after the person acquired the facility. *See* 42 U.S.C. § 9601(40)(B)(i). Regarding the limited exclusion for State and local governments, they cannot have caused or contributed to the release or threatened release of a hazardous substance from the facility. *See* 42 U.S.C. § 9601(20)(D).

years and beyond. Because EPA does not plan to release its Interim Guidance on Destroying and Disposing of Certain PFAS until Fall 2023,[107] EPA has provided no final indication that existing hazardous waste disposal capacity can handle the increased disposal volumes for wastes containing PFOA and PFOS. EPA's 2019 Assessment of National Capacity for Hazardous Waste Management stated "that adequate national capacity for the treatment and disposal of hazardous waste exists… through the year 2044," which means that EPA may not be able to satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes beginning in 2025.[108] Because that Assessment did not consider how the volume of hazardous wastes will increase dramatically if PFOA and PFOS are designated as CERCLA hazardous substances, EPA cannot guarantee it can satisfy CERCLA's mandatory 20-year period of sufficient capacity for hazardous wastes from today. EPA has acknowledged that it has required PFOA and PFOS cleanup at sites already by asserting that they are CERCLA pollutants or contaminants. However, it has not described disposal methods for contaminated soils or other media from the new sites that would be created if this rule is finalized.

Additionally, EPA has not disclosed any agreement with any state to ensure that the state has adequate capacity to destroy, treat, or securely dispose of all the materials contaminated with PFOA and PFOS in any period in the future.[109] There are currently an incineration capacity challenges that would certainly be exacerbated by this proposal. Biosolids may contain some amount of PFOA and PFOS, are generated nationally at a rate of approximately 4.5-6 million metric short tons annually and may necessitate specialized disposal solutions in some cases. EPA has failed to establish the adequacy of states' existing capacity to destroy, treat, or securely dispose of quantities of materials contaminated with PFOA and PFOS. In fact, to the extent that certain waste streams with elevated levels of PFOA and PFOS require management at a RCRA Subtitle C hazardous waste facility, all indications suggest that existing capacity would prove decidedly inadequate in short order and that waste streams from DoD facilities alone might be close to or even exceed capacity, with only a small amount remaining for any private requirements. EPA must finalize the Interim Guidance on Destroying and Disposing of Certain PFAS and estimate available waste disposal capacity before this proposed rule is finalized.

4. The Listing Will Impact Public Safety

When confronted with fire emergencies, airports, oil and gas facilities, the industrial sector, the shipping industry, and the U.S. military (including DoD, Navy, and Air Force) are among the many sectors that have historically used PFOA- and PFOS-containing aqueous film forming foams (AFFF) because they are proven effective at protecting life and critical infrastructure. The proposed rule fails to acknowledge how and why PFAS-containing AFFF are used, particularly that they are deployed at highly diluted concentrations in emergency firefighting situations. In the event of an emergency involving a hydrocarbon fire, firefighting

---

[107] *See* EPA, "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024" at 17, *available at* https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.
[108] *See* EPA, "National Capacity Assessment Report, Pursuant to CERCLA Section 104(c)(9),"
[109] We are aware that some states and local governments are currently shipping or considering shipping PFAS-containing material to Subtitle C disposal facilities many hundreds of miles away to other states.

foams that allow swift and definitive extinguishing power are required to protect the lives of first responders, workers, and the public, as well as the environment.

The proposed rule also fails to acknowledge that firefighting capacity is critical to ensuring stable operation for the entire oil and gas industry, which, as part of the energy sector, is designated critical infrastructure by the Cybersecurity and Infrastructure Security Agency (CISA) under Presidential Policy Directive 21 (PPD-21).[110] Critical infrastructure is those "assets, systems, and networks, whether physical or virtual, … considered so vital to the United States that their incapacitation or destruction would have a debilitating effect on security, national economic security, national public health or safety, or any combination thereof."[111]

EPA must allow for an adequate period of time to elapse for any transition to fluorine-free firefighting foams: a minimum 3 to 5 years is necessary. EPA should also consider either appropriate exclusions for life-saving firefighting operations or modifying the listing in another manner such that reporting obligations and liability related to the use of fluorine foams are not imposed before users of these foams have an adequate time to make the transition.

C. EPA Cannot Appropriately Manage the Overbreadth of a CERCLA Section 102(a) Listing by Using Enforcement Discretion

Following the publication of this proposed rule, EPA made assurances to the regulated community that it plans to exercise its enforcement discretion and other approaches to ensure "fairness for minor parties who may have been inadvertently impacted by [PFOA and PFOS] contamination."[112] EPA has offered these remarks to assuage equity concerns expressed by small entities and certain industries and sectors, including public water utilities, municipal airports, and entities that use biosolids.[113] EPA asserts that it will also resolve issues on a "site-specific basis," and that it will seek to address potential liability on "equitable considerations" to protect certain parties from litigation by those "principally responsible for PFOA and PFOS contamination, and minimize transaction costs."[114]

While we appreciate EPA's awareness of potential equity issues that can arise with certain PRPs in the context of CERCLA enforcement, promises of enforcement discretion on a

---

[110] In 2015 the Department of Homeland Security stated: "The Energy Sector consists of widely-diverse and geographically-dispersed critical assets and systems that are often interdependent of one another. This critical infrastructure … include[s] the production, refining, storage, and distribution of oil, gas, and electric power…. The Energy Sector supplies fuels to the transportation industry, electricity to households and businesses, and other sources of energy that are integral to growth and production across the Nation." U.S. Department of Homeland Security, *Energy Sector-Specific Plan 2015,* https://www.cisa.gov/sites/default/files/publications/nipp-ssp-energy-2015-508.pdf.

[111] *See* https://www.cisa.gov/critical-infrastructure-sectors.

[112] *See* EPA news release "EPA Proposes Designation Certain PFAS Chemicals as Hazardous Substances Under Superfund to Protect People's Health" (Aug. 26, 2022) https://www.epa.gov/newsreleases/epa-proposes-designating-certain-pfas-chemicals-hazardous-substances-under-superfund.

[113] *See* EPA, presentation "Notice of Proposed Rulemaking: Designating PFOA and PFOS as CERCLA Hazardous Substances" (Aug. 2022), https://www.epa.gov/system/files/documents/2022-09/Overview%20Presentation_NPRM%20Designation%20of%20PFOA%20and%20PFOS%20as%20CERCLA%20Hazardous%20Substances.pdf.

[114] *Id*.

case-by-case basis are no substitute for explicit regulatory exclusions from liability, which EPA believes it does not have the authority to provide.[115] The possibility of enforcement discretion provides no comfort to small entities, public utilities, and waste management facilities, who are at the mercy of changes in EPA position as agency leadership and priorities evolve over time. These entities are still left without certainty or the ability to predict what this enforcement discretion will cover and in what circumstances they can expect to see relief.

Even as it stands today, EPA has a policy against providing definitive assurances outside of the context of a formal enforcement proceeding.[116] EPA takes the position that such "no action assurances" erode the credibility of EPA's enforcement program by creating real or perceived inequities in the treatment of the regulated community and may hamper future enforcement efforts against a party who relies on that assurance.[117] The only exception EPA provides is for "extremely unusual cases" in which a "no action assurance" policy is "clearly necessary to serve the public interest."[118] EPA has explicitly affirmed that its general policy concerning "no action assurances" applies to sites subject to CERCLA.[119]

Given the number of new sites that may be reopened or investigated following EPA's listing of PFOA and PFOS as hazardous substances under CERCLA, it is questionable whether EPA will have the resources to properly handle the influx of new cases and new PRPs who will need specific case-by-case consideration for enforcement discretion.

IV. The Proposed Rule Fails to Provide Sufficient Explanation and Justification for EPA's Novel Proposed Use of its Authority

A. The Proposed Rule Does Not Explain EPA's Position on What Constitutes a "Substantial Danger," the Statutory Standard for Designating a Hazardous Substance

CERCLA Section 102(a) authorizes EPA to designate as "hazardous substances" substances that "when released into the environment may present substantial danger to the public health or welfare or the environment…."[120] The statute does not define this standard, and EPA has not previously provided an interpretation for this standard because it has never exercised this authority. Because EPA is exercising this authority for the first time, it must provide the public with a reasonable explanation of how the standard operates, any limiting principles that apply to its use, and the agency's reasoning as to why PFOA and PFOS meet this standard. It is axiomatic that EPA, as the agency charged with administering this section of the statute, has the burden to provide a reasoned explanation for its action and for its construction of the relevant provision, which in this case requires clearly explaining what criteria are to be used in determining that a

---

[115] *Id*. ("EPA does not have authority to exempt particular entities from liability.")
[116] Memorandum from Courtney M. Price, Assistant Administrator for enforcement and Compliance Monitoring to Assistant Administrators, Regional Administrators, General Counsel, and Inspector General, "Policy Against "No Action Assurances," November 16, 1984: https://www.epa.gov/enforcement/guidance-no-action-assurances-policy.
[117] *Id*.
[118] *Id*.
[119] Memorandum from Barry Breen, "Applicability of Policy Against 'No Action' Assurances to CERCLA," June 16, 2000: https://www.epa.gov/enforcement/guidance-applicability-policy-against-no-action-assurances-cercla.
[120] 42 U.S.C. § 9602(a).

substance "may present" a "substantial danger" for purposes of CERCLA.[121] The proposed rule makes little attempt to shed light on how EPA exercised its discretion in Section 102(a), leaving the regulated community unable to understand its reasoned basis for listing PFOA and PFOS.

EPA attempts to justify listing PFOA and PFOS as CERCLA hazardous substances by describing the characteristics of these substances, and then, without connecting those chemical properties to any risk of exposure, it simply labels these characteristics as creating "substantial danger." The logical gap between the descriptions and the conclusion must be filled by reasoning that is subjected to public comment. Moreover, EPA's approach (to the extent it can be discerned at all) appears to conflate two regulatory principles that it carefully distinguishes in other contexts, hazard and risk.[122] Many chemicals present a hazard to human health if ingested in sufficient amounts, but few present a potential level of exposure that warrants triggering new nationwide cleanup liability. EPA evades providing an interpretation of the statutory standard that would enable one to distinguish PFOA and PFOS from many other chemicals that, presumably, do not satisfy the standard. Additionally, EPA provides no discernable criteria that can be applied to other substances going forward. EPA must explain the statutory standard under CERCLA and then justify why PFOA and PFOS are appropriate candidates for listing based on that standard. Without providing a sufficient explanation of the standard, EPA's decision to list PFOA and PFOS is arbitrary and an invalid exercise of agency discretion.

It bears emphasis that EPA must fully explain its interpretation of Section 102(a) to afford stakeholders the opportunity to comment, including commenting on the criteria as applied to PFOA and PFOS. The failure to provide this opportunity violates the APA's public notice requirements. How EPA applies its criteria is not only highly consequential for these substances, but it is also precedent setting, as EPA has never wielded this authority in the more than 40 years since CERCLA's enactment. This proposed rulemaking would affect a broad set of stakeholders beyond those simply interested in PFOA and PFOS because it will affect EPA decisions on future hazardous substance listing decisions. EPA has already announced plans to release an advance notice of proposed rulemaking to add more PFAS as hazardous substances under Section 102(a). It must provide a reasoned explanation of how to apply this standard beyond a bare assertion that PFOA and PFOS may have human health effects, and that the chemicals may move through the environment.

1. EPA Fails to Provide its Interpretation of the "May Present a Substantial Danger" Standard Under CERCLA

In this proposed rule, EPA fails to provide clear parameters or guidance on the meaning of the "may present a substantial danger" standard under CERCLA Section 102(a). The only "considerations" EPA articulates for this standard are as follows:

---

[121] *See Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984) (judicial review under APA requires assessment of appropriateness of agency's construction of statute); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 42 (1983) (presumption for judicial review is against agency changes in current policy that are not justified by the rulemaking record).

[122] Risk is a concept that integrates hazard and exposure. See, for example, EPA's procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,752 (Jul. 20, 2017), under which risk characterization requires integration of hazard and exposure.

> In assessing whether a substance, when released, may present "substantial danger," the EPA proposes to consider information such as the following: the potential harm to humans or the environment from exposure to the substance (*i.e.,* hazard), and how the substance moves and degrades when in the environment (*i.e.,* environmental fate and transport). To further inform its decision about whether the statutory factors have been met, the Agency proposes to also consider other information that may be relevant when evaluating releases of the substance, such as the frequency, nature, and geographic scope of releases of the substances. The Agency proposes to weigh this information to determine whether the substance, when released, may present a "substantial danger."[123]

The language of the "information" about the "statutory factors" that EPA will consider is all forward looking, indicating that EPA has not yet undertaken the task of applying the level of "harm to humans or the environment from exposure" or the "environmental fate and transport" to PFOA and PFOS. EPA also proposes to address the "frequency, nature, and geographic scope of releases of the substances" but gives no indication in the proposal that it has attempted any effort to characterize where and how PFOA and PFOS exist in the environment. This raises a host of questions and uncertainties that must be answered if EPA were to attempt to adopt a reasonably discernible standard. While the proposal, relying on EPA's Health Advisories, provides information on potential harm to humans, it offers little on estimated exposure from contaminated sites. There is no mapping of expected PFOA and PFOS releases or how those releases are a threat to public health, in what frequencies, at what level, in what medium, and over what period of time. EPA's rationale does not provide stakeholders with nearly enough information to begin to evaluate these questions. EPA's explanation is vague and sheds even less light on how this information will be "weighed" against the poorly defined list of considerations.

In interpreting the "may present a substantial danger" standard under CERCLA, EPA must consider how the hazardous substance listing warrants use of its full authorities under CERCLA to address the "substantial danger" to public health and welfare or the environment. As discussed, in the proposed rule, the only considerations EPA would "weigh" in deciding to list a substance under the "substantial danger" standard are hazard, environmental fate and transport, and the frequency, nature, and geographic scope of releases of the substances. However, EPA does not explain how each of these considerations affects the listing decision. Further, EPA does not explain why PFOA and PFOS present hazards at a frequency, nature, and scope that "may present a substantial danger" to the public or the environment in the context of CERCLA, meaning *from contaminated sites*. Indeed, it would be quite difficult for EPA to argue that raindrops, which could contain PFOA and PFOS,[124] present a "substantial danger."

---

[123] 87 Fed. Reg. at 54,421.

[124] Ian T. Cousins, Jana H. Johansson, Matthew E. Salter, Bo Sha, and Martin Scheringer, *Environmental Science & Technology* 2022 56 (16), 11172-11179, https://doi.org/10.1021/acs.est.2c02765; Karen Y. Kwok, Sachi Taniyasu, Leo W. Y. Yeung, Margaret B. Murphy, Paul K. S. Lam, Yuichi Horii, Kurunthachalam Kannan, Gert Petrick, Ravindra K. Sinha, and Nobuyoshi Yamashita, *Environmental Science & Technology* 2010 44(18), 7043-7049, https://doi.org/10.1021/es101170c; Seung-Kyu Kim and Kurunthachalam Kannan, *Environmental Science & Technology* 2007 41(24), 8328-8334, https://doi.org/10.1021/es072107t.

2. The Proposed Rule Appears to Improperly Conflate Any Chemical with a Hazard Profile as a Chemical That Warrants a Hazardous Substance Listing Under CERCLA

In lieu of a reasoned explanation of the statutory standard for "may present a substantial danger," EPA merely summarizes the chemical and physical characteristics, toxicity and toxicokinetics, and environmental prevalence of PFOA and PFOS and concludes the summary with blanket statements that this information "demonstrates" that PFOA and PFOS should be designated as hazardous substances under CERCLA.[125] EPA makes conclusory statements that the "totality of the evidence" indicates that PFOA and PFOS may present substantial danger, and that "[t]his level of evidence is more than sufficient to satisfy the CERCLA section 102(a) standard. EPA believes that *this amount and type* of evidence exceeds the minimum required under CERCLA section 102(a)" (emphasis added).[126]

EPA has not given stakeholders any indication of what "amount and type of evidence" is required to "exceed the minimum required" under CERCLA. The agency identifies scientific evidence about PFOA and PFOS exposures (with the acknowledgement that the science is still evolving)[127] but fails to explain why and how this evidence "may present a substantial danger" to public health or the environment.

Thus, EPA appears to work backwards in the proposed rule by explaining what it believes are the characteristics and hazards of PFOA and PFOS and justifying their listing based on these characteristics specific to PFOA and PFOS, rather than first establishing the statutory standard with specific criteria and then determining if PFOA and PFOS meet these criteria for listing. The latter approach is consistent with good practices and sound public policy; the former approach – particularly in this context, where the standard is being applied for the first time – risks arbitrary outcomes and is legally insufficient.

EPA must interpret the "may present a substantial danger" standard based on the purpose and intent of hazardous substance designations under CERCLA and then evaluate whether PFOA and PFOS are appropriate for listing. The vague and broad nature of EPA's rationale would surely allow EPA to list a wide range of chemicals, including many persistent and bioaccumulative substances, as hazardous substances. Yet many of these same substances would never meet a reasonable definition of "substantial danger."

As EPA describes in the preamble, CERCLA was enacted to promote the timely cleanup of contaminated sites and provide the federal government with authority to respond to releases or threatened releases of hazardous substances in order to protect the public health and the environment.[128] Key to considering a chemical as a hazardous substance, which could trigger not only reporting requirements but also potential financial liability for property owners to perform remediation of PFOA and PFOS present on their property, is that the hazardous substance presents a "substantial danger" to public health and the environment within the context of

[125] 87 Fed. Reg. at 54,429.
[126] *Id*. at 54,416.
[127] *Id*. at 54,423.
[128] *Id*. at 54,420.

CERCLA's authority. In this context, Congress did not intend for CERCLA authority to address every chemical substance with a hazard profile. Otherwise, any chemical substance would be eligible for a CERCLA hazardous substance designation because virtually any substance could potentially pose a "hazard" to public health or the environment. EPA does not even describe how potential PFOA and PFOS exposure levels lead to risk levels sufficient to meet the standard. As drafted, the proposal has the potential to open and reopen numerous Superfund sites based on any presence whatsoever of PFOA and PFOS on the property, which could have originated from any number of sources.

Since EPA can use its authority under CERCLA to compel site cleanup (or cost recovery for site cleanup), EPA must explain why PFOA and PFOS may present a substantial danger to public health and the environment *from contaminated sites*. EPA acknowledges in the proposed rule that there are numerous uncertainties in how many sites could be impacted, including:

(1) how many sites have PFOA or PFOS contamination at a level that warrants a cleanup action;
(2) the extent and type of PFOA and PFOS contamination at/near sites;
(3) the extent and type of other contamination at/near sites;
(4) the incremental cost of assessing and remediating the PFOA and/or PFOS contamination at/near these sites; and
(5) the cleanup level required for these substances.[129]

EPA claims that it cannot know how many sites could have PFOA and PFOS contamination, and therefore it cannot know to what extent the substances are present, which sites will require cleanup, and how much human or environmental exposure there is to these substances from these sites. Without a diligent attempt at answering these questions (including using quantification techniques as appropriate), EPA cannot demonstrate (how EPA interprets the statutory standard) that PFOA and PFOS "may present a substantial danger" to public health or the environment under CERCLA. EPA must attempt to evaluate existing data sources on known PFOA and PFOS exposures, including, as appropriate, the use of modeling efforts that are available to EPA to assess these questions, as the Chamber did for non-federal Superfund sites. EPA's decision to designate PFOA and PFOS as hazardous substances under CERCLA is arbitrary. EPA should withdraw this rulemaking until it completes a more comprehensive assessment of likely nationwide occurrences of PFOA and PFOS and address other uncertainties we raised in our October 18, 2022, letter. EPA should not guess for the purposes of this rulemaking about the extent of PFOA or PFOS pollution at contaminated sites; the stakes are too high.

3. The Proposed Rule Provides No Basis for Determining Which Chemicals Could Be Listed Under CERCLA Section 102(a)

Under the current CERCLA regime, which has been successful for many years without resorting to Section 102(a), stakeholders have a level of predictability because the hazardous substance definition incorporates lists of chemicals from other statutes that either adopt lists

[129] *Id*. at 54,423.

designated by statute or have more specific criteria for the types of hazards or risk that is contemplated:

- Any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act [33 U.S.C. § 1321(b)(2)(A)];

- Any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act [42 U.S.C. 6921] (but not including any waste the regulation of which under the Solid Waste Disposal Act [42 U.S.C. § 6901 et seq.] has been suspended by Act of Congress);

- Any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act [33 U.S.C. § 1317(a)], (E) any hazardous air pollutant listed under section 112 of the Clean Air Act [42 U.S.C. § 7412];

- Any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act [15 U.S.C. § 2606]….[130]

Congress failed to supply as precise a definition in Section 102(a), but it did not grant unbridled discretion to EPA. EPA must, at a minimum, provide a similar level of predictability for future designations of hazardous substances by clearly defining the criteria in Section 102(a), recognizing where it differs from the other statutory mechanisms that are imported by CERCLA. Without a clear articulation of the Section 102(a) standard before making a Section 102(a) designation, potentially any chemical substance, including chemicals identified on a hazardous substance list or chemical of concern list generated by another state, federal, or international agency, could be designated as a CERCLA hazardous substance at any time. EPA could choose to consider only "the potential harm to humans or the environment *from exposure* to the substance (i.e., hazard)" (emphasis added) in making such a designation decision. Under an uncertain and unbounded standard, businesses, non-profits, and property owners across the country would face potentially significant liability and little certainty as to when and how liability could arise.

B. EPA's Definition of "Hazardous Substance" Must Be Informed by the Statute's Treatment of "Pollutants and Contaminants"

1. Congress Drafted CERCLA to Require "Hazardous Substances" to Be More Than Mere "Pollutants or Contaminants" Reasonably Anticipated to Cause Harm to Human Health

CERCLA authorizes EPA to clean up both "hazardous substances" and "pollutants or contaminants," but places heightened priority and legal liabilities for "hazardous substances." In defining the term "pollutant or contaminant," Congress did not adopt simpler definitions of pollutants or contaminants from other major federal environmental statutes, such as the CAA,

[130] 42 U.S.C. § 9601(14).

academic any further discussion about whether the danger their release might pose would be significant or insignificant.

The fact that EPA is choosing to exert authority it has never previously used to designate as CERCLA hazardous substances PFOA and PFOS, two substances it has not shown causes death or illness, suggests the inappropriateness of EPA's proposed designation here. Allowing EPA to designate PFOA and PFOS as CERCLA "hazardous substances" without first establishing that they are CERCLA "pollutants or contaminants" ignores the structure that Congress intentionally embedded in CERCLA.

CERCLA Section 107(a) assigns PRP liability only to owners, operators, arrangers, and transporters of "hazardous substances," not of "pollutants or contaminants," or even of "pollutants or contaminants which may present an imminent and substantial danger to the public health or welfare."[145] EPA should interpret the "substantial danger" standard in light of the fact that it is unlikely that Congress intended to grant it authority to assign PRP liability for a chemical that it has not yet explained thoroughly qualifies as a "pollutant or contaminant." EPA should not skip over these lower determinations and jump straight to declaring that PFOA and PFOS are "hazardous substances" under CERCLA Section 102(a).

C. Section 102(a) Requires Consideration of Costs in Making the Listing Decision

EPA's position that it may not, and need not, consider cost when adopting a rule designating PFOA and PFOS to be hazardous substances pursuant to CERCLA Section 102(a) is deeply flawed and contrary to the Supreme Court precedent it cites as justification for its position. Not only does CERCLA Section 102(a) *allow* costs to be considered, but it also *requires* that EPA do so. EPA's reading of the statutory text to preclude consideration of costs is in direct tension with cases, starting with *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co*., 463 U.S. 29 (1983), through *Michigan v. EPA*, 576 U.S. 743 (2015), that find that agencies should consider the costs and benefits of their actions absent statutory text to the contrary.[146] EPA's interpretation of CERCLA Section 102(a) is also belied by the alternative paths by which other substances may be designated as hazardous under CERCLA.

1. U.S. Supreme Court Precedent Establishes that EPA May Consider Costs Even When a Statute Is Silent and *Must* Consider Costs When Certain Broad Language Is Used by Congress

Three relatively recent and highly relevant U.S. Supreme Court cases have considered the direct question of whether EPA must consider costs when applying standards in other similar statutes: *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001); *Entergy Corp. v.*

[145] *See* 42 U.S.C. § 9607(a).

[146] "Indeed, we do not quibble with [Judge Kavanaugh's] general premise—and that of the many legal luminaries he cites—that an agency should generally weigh the costs of its action against its benefits." *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 723 (D.C. Cir. 2016) (responding to dissent, which argued that cost consideration was required).

Riverkeeper, Inc., 556 U.S. 208 (2009); and *Michigan v. EPA*, 576 U.S. 743 (2015).[147] In *American Trucking*, EPA was precluded from considering costs; in *Entergy Corp.*, EPA was permitted to consider costs; and in *Michigan*, EPA was compelled to consider costs.

The CAA requires that, for certain listed air pollutants, EPA must issue air quality criteria for them based on factors relating to how each pollutant's presence in the atmosphere might affect public health or welfare.[148] Moreover, when EPA prescribes national primary ambient air quality standards (NAAQS) for certain air pollutants, CAA Section 109(b)(1) describes what EPA must consider in their establishment:

> ***National primary ambient air quality standards***, prescribed under subsection (a) ***shall be ambient air quality standards*** the attainment and maintenance of which in the judgment of the Administrator, ***based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health***. Such primary standards may be revised in the same manner as promulgated.

The Supreme Court held in *American Trucking* that EPA could not consider costs when setting NAAQS because cost considerations (including any balancing of costs and benefits) are not a criterion or consideration relating to public health.[149]

Subsequently, in *Entergy Corp. v. Riverkeeper, Inc.*, the Supreme Court upheld EPA's interpretation that it could consider cost as a factor in setting standards under CWA Section 316(b) for the design and operation of power plant cooling water intake structures to minimize adverse impacts to aquatic life, even where the statute was completely silent as to cost consideration. The statutory provision said:

> Any standard established pursuant to section 1311 of this title or section 1316 of this title and applicable to a point source shall require that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available for minimizing adverse environmental impact.[150]

The Court reasoned "that [CWA] § 1326(b)'s silence [as to cost] is meant to convey nothing more than a refusal to tie the agency's hands as to whether cost-benefit analysis should be used, and if so to what degree."[151] The Court also found that *American Trucking* "stands for the rather unremarkable proposition that sometimes statutory silence, when viewed in context, is best interpreted as limiting agency discretion."[152]

Finally, the Supreme Court addressed in *Michigan v. EPA* what type of statutory language affirmatively implies that cost must be considered by the agency. All nine Justices in

---

[147] For a broader discussion of cases where benefit-cost analysis was found to be integral to particular environmental statutes, see *Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process*, 85 Fed. Reg. 84,130, 84,131-35 (Dec. 23, 2020).
[148] *See* 42 U.S.C. § 7408(a)(2).
[149] *Am. Trucking Ass'ns*, 531 U.S. at 465.
[150] 33 U.S.C § 1326(b).
[151] *Entergy Corp.* 556 U.S. at 222; *see also id.* at 212, 219-20, 226.
[152] *Id*. at 223.

Michigan agreed that "[c]ost is almost always a relevant—and usually, a highly important—factor in regulation. Unless Congress provides otherwise, an agency acts unreasonably in establishing 'a standard-setting process that ignore[s] economic considerations.'"[153]

At issue was what the CAA authorized EPA to consider when adding power plants as a category of sources of hazardous air pollutants. The statutory provision at issue in *Michigan* uses the words "appropriate and necessary" and does not expressly reference cost in the list of factors the agency must consider.[154] In its Mercury and Air Toxics rulemaking, EPA had concluded that, when adopting regulations for emissions by electric utility steam generating units ("power plants"), EPA was not required to consider costs.[155] CAA Section 112(n)(1)(A) states:

> The Administrator shall perform a study of the hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units of pollutants listed under subsection (b) after imposition of the requirements of this chapter. … The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is ***appropriate and necessary*** after considering the results of the study required by this subparagraph.[156]

The Supreme Court reviewed EPA's interpretation under its *Chevron* standard and concluded that EPA's refusal to consider costs reflected an unreasonable interpretation of the statute.[157] Although EPA must consider study results of hazards to public health reasonably anticipated to occur from power plant emissions, "Congress instructed EPA to add power plants to the program if (but only if) the Agency finds regulation 'appropriate and necessary.' … In particular, 'appropriate' is 'the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors.'"[158]

Inclusion of "appropriate" in the statute "requires at least some attention to cost," and "an agency may not 'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate."[159] The Supreme Court made clear the distinction between the statute at issue in *Michigan* and the CAA provision it assessed fourteen years earlier:

> *American Trucking* thus establishes the modest principle that where the Clean Air expressly directs EPA to regulate on the basis of a factor that on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway. That principle has no application here. "Appropriate and necessary" is a far more comprehensive criterion than "requisite

[153] *Michigan*, 576 U.S. at 769 (dissenting opinion of Justice Kagan).
[154] *Id.* at 751-53.
[155] *Id.* at 749.
[156] 42 U.S.C. § 7412(n)(1)(A) (emphasis added).
[157] *Michigan*, 576 U.S. at 751 (citing *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (2015)).
[158] *Id.* at 752 (quoting *White Stallion Energy Center, LLC v. EPA*, 748 F.3d 1222, 1266 (D.C. Cir. 2014) (opinion of Kavanaugh, J.)).
[159] *Id.* (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

to protect the public health"; read fairly and in context, as we have explained, the term plainly subsumes consideration of cost.[160]

2. The Analysis in *Michigan v. EPA* Governs CERCLA Section 102(a), Requiring EPA to Consider Cost When Adopting Rules Revising the CERCLA Hazardous Substances List

Given the specific language in CERCLA Section 102(a), which resembles CAA Section 112(n)(1)(A), the holding in *Michigan* compels EPA to consider costs when designating PFOA and PFOS as hazardous substances. Congress expanded EPA's discretion to revise the list of substances deemed to be hazardous substances by including "appropriate" in CERCLA Section 102(a):

> The Administrator shall ***promulgate and revise as may be appropriate***, regulations designating as hazardous substances, in addition to those referred to in section 9601(14) of this title, such elements, compounds, mixtures, solutions, and substances which, when released into the environment may present substantial danger to the public health or welfare or the environment, and shall promulgate regulations establishing that quantity of any hazardous substance the release of which shall be reported pursuant to section 9603 of this title.[161]

Like the CAA provision assessed in *Michigan*, Congress authorized EPA to revise the list of hazardous substances "as may be appropriate," and EPA's obligation to consider a substance's potential for presenting "substantial danger to the public health or welfare or the environment" is similar to EPA's obligation under CAA Section 112(n)(1)(A) to consider a study of a given pollutant's hazard to public health reasonably anticipated to occur from power plant emissions. Moreover, the logic of *American Trucking* is inapplicable to CERCLA Section 102(a) because, unlike the relevant provision of CAA Section 109(b)(1), which was referenced by CAA Section 109(d) expressly,[162] CERCLA Section 102(a) does not limit the criteria EPA may consider in designating hazardous substance to only "such criteria … requisite to protect public health" or some similar term. Nor did Congress expressly preclude EPA from considering costs in making the determinations specified in CERCLA Section 102(a).

EPA's justification for ignoring cost considerations when deciding to designate PFOA and PFOS as CERCLA hazardous substances pursuant to CERCLA Section 102(a) ignores critical details in the statutes and cited court opinions, resulting in a legal assessment divorced

---

[160] *Id.* at 755-56 (quoting *Am. Trucking*, 531 U.S. at 467).

[161] 42 U.S.C. § 9602(a) (emphasis added). The language in CERCLA Section 102(a) also mirrors that of CWA Section 311(b)(2)(A), and EPA's consideration of costs when designated substances to be hazardous under that statute predate the passage of CERCLA itself. *Compare* 33 U.S.C. § 1321(b)(2)(A); *see* 43 Fed. Reg. 10,474, 10,479 (March 13, 1978) (when EPA first published its proposed regulations for CWA § 311 hazardous wastes, EPA had already "determined that the economic impact of the designation of hazardous substances could not be separated from a consideration of removability, harmful quantities and rates of penalty.").

[162] "[T]he Administrator shall complete a thorough review of the criteria published under section 7408 of this title and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards ***as may be appropriate in accordance with section 7408 of this title and subsection (b) of this section***." 42 U.S.C § 7409(d)(1)(emphasis added)

from applicable law. EPA cherry-picks language from *American Trucking* to create a false impression that whenever Congress authorizes EPA to consider public health and welfare while making regulatory decisions, cost should be precluded.[163] CAA Section 109(b)(1), quoted in context, unlike the edited quote in the proposal, illustrates the stark difference between that statute and CERCLA Section 102(a). As *American Trucking* observes:

> Section 109(b)(1) instructs the EPA to set primary ambient air quality standards "the attainment and maintenance of which… are requisite to protect the public health" with "an adequate margin of safety."[164]

EPA incorrectly suggests that CERCLA Section 102(a) is similar to the quite different statutory provision that was at issue in *American Trucking*. Far from employing even remotely similar language, CERCLA Section 102(a) does not identify any standards to which hazardous substances should be subject; EPA acknowledges that "determinations of *whether and how to address* something hazardous" occur later "in the context of response actions," in which EPA might consider costs.[165] Unlike CAA Section 109(b)(1), CERCLA Section 102(a) delegates to EPA the discretionary authority to designate a substance as a CERCLA hazardous substance, not a mandatory duty to establish numeric limits "requisite" to protect the public health. If, instead, CERCLA Section 102(a) created a nondiscretionary duty for EPA to designate as a "hazardous substance" ***all*** "elements, compounds, mixtures, solutions, and substances which, when released into the environment ***may*** present substantial danger to the public health or welfare or the environment…," table salt might have to be listed under this section, because freshwater fish would certainly face "substantial danger" if an errant truckload of sodium chloride crashed into their pond.[166] EPA acknowledges the holding in *Michigan* that Congress' inclusion of the broad term "appropriate" requires "consideration of all the relevant factors," including "at least some attention to cost."[167] As for the presence of "appropriate" in CERCLA Section 102(a), EPA confusingly asserts that it "is not used in the context of what EPA should consider when assessing whether a substance is hazardous," but then says CERCLA Section 102(a) commands it to "promulgate and revise as may be appropriate regulations that accomplish the statutory goal of designating hazardous substances."[168] As the words are literally identical, this falls short of even the proverbial "distinction without a difference."[169]

EPA's final attempt to justify its decision to ignore cost considerations is by analogy to RCRA. In *Utility Solid Waste Activities Group v. EPA*, the D.C. Circuit held that

> Under any reasonable reading of RCRA, there is no textual commitment of authority to the EPA to consider costs in the open-dump standards. RCRA's statutory language instructs the EPA to classify a disposal site as a sanitary landfill and not an open dump only "if there is no reasonable probability of

[163] *See* 87 Fed. Reg. at 54,421(quoting *Am. Trucking*, 531 U.S. at 465).
[164] *Am. Trucking*, 531 U.S. at 465 (quoting 42 U.S.C. § 7409(b)(1)).
[165] 87 Fed. Reg. at 54,421 (emphasis in original).
[166] CERCLA § 102(a), 42 U.S.C. § 9601(a) (emphasis added).
[167] 87 Fed. Reg. at 54,421 (quoting *Michigan*, 576 U.S. at 752).
[168] 87 Fed. Reg. at 54,421.
[169] *Sessions v. Dimaya*, 584 U.S. __, 138 S. Ct. 1204, 1218 (2018).

> ***adverse effects on health or the environment*** from disposal of solid waste at such facility."[170]

Yet, in the following sentence, the D.C. Circuit distinguished *Michigan* because the RCRA statute lacked "any flexible language such as 'appropriate and necessary' that might allow the EPA to consider costs in its rulemaking."[171] As CERCLA Section 102(a) unquestionably states that EPA may designate substances as CERCLA "hazardous" substances "*as may be appropriate*," (emphasis added), CERCLA Section 102(a) is closer to the CAA provision in *Michigan* than to the RCRA provision in *Utility Solid Waste Activities Group*, which in turn reflects the same principle that was dispositive in *American Trucking*.

3. CERCLA "Hazardous Substances" Automatically Include Hazardous or Toxic Wastes and Pollutants Pursuant to Other Federal Environmental Regulatory Laws, the Designations of Which Sometimes Require Considerations of Cost

In addition to Congress' delegation of authority to EPA to add substances to the list of hazardous substances under CERCLA Section 102(a), CERCLA's definition of "hazardous substance" requires automatic inclusion of certain substances declared to be hazardous or toxic wastes or pollutants pursuant to other federal environmental regulatory laws.[172] At least one of these provisions clearly requires EPA to consider costs; it contains the same operative language as does CERCLA Section 102(a).

a. CWA Section 311(b)(2)(A) Requires EPA to Consider Costs

Congress appeared to model the statutory language in CERCLA Section 102(a) on CWA Section 311(b)(2)(A), which requires, in pertinent part, that EPA:

> [S]hall ***develop, promulgate, and revise as may be appropriate*** regulations designating as hazardous substances…, such elements and compounds which, when discharged in any quantity into or upon the navigable waters of the United States or adjoining shorelines… present an imminent and substantial danger to the public health or welfare, including but not limited to fish, shellfish, wildlife, shorelines, and beaches.[173]

Although Congress instructed EPA to assess whether substances may "present an imminent and substantial danger to the public health or welfare," the fact that Congress authorized EPA to "develop, promulgate and revise" this hazardous substances list "as may be appropriate," requires application of the analysis in *Michigan*, not *American Trucking*. Therefore, EPA must consider costs when revising the list of CWA Section 311(b)(2)(A) hazardous substances.[174]

---

[170] 901 F.3d 414, 448-449 (D.C. Cir. 2018) (emphasis in original) (quoting 42 U.S.C. § 6944(a)).
[171] *Id.* at 449 (quoting *Michigan*, 576 U.S. at 756, 135 S. Ct. at 2709).
[172] 42 U.S.C. § 9601(14).
[173] 33 U.S.C. § 1321(b)(2)(A) (emphasis added).
[174] The same basic reasoning and analysis likewise apply to RCRA Section 3001(b). See RCRA § 3001(b)(1).

Indeed, EPA has considered costs when assessing substances for designation as CWA Section 311 hazardous substances since before the program was implemented. On December 30, 1975, when EPA first published its proposed regulations for CWA Section 311 hazardous wastes, EPA had already "determined that ***the economic impact of the designation of hazardous substances could not be separated from a consideration of removability, harmful quantities and rates of penalty***."[175] The fact that the "economic impact of the proposed regulations was not considered major" did not excuse EPA from conducting the economic analysis at all.[176]

Moreover, as part of EPA's initial designation of hazardous substances in 1978, EPA prioritized regulation of "materials of relatively low market price and relatively high toxicity, i.e., meeting the toxicological selection criteria" by considering the value of the product to be regulated.[177] For sufficiently toxic candidate substances with annual production of less than one billion pounds annually:

> the selling price of the substance at the first commercial market level was examined. Available evidence appeared to indicate that substances with relatively high selling prices had a smaller discharge frequency, since more expensive chemicals are generally packaged and shipped in smaller quantities, and with greater precautions. If a candidate substance had a high selling price relative to the majority of substances, it was not further considered for testing.[178]

In this way, the financial value of the substances subjected to regulation was deemed by EPA to be inversely proportional to the substances' need for regulation. For example, EPA maintained ammonium bicarbonate's designation as a hazardous substance because its "diverse industrial use," 16 million pound annual production, and "low selling price of \$0.10 to \$0.12 per pound" indicated "a reasonable discharge potential."[179] Conversely, EPA agreed to delete antimony pentafluoride from the designation list because its "annual production quantities of less than 5,000 pounds and a selling price of \$15 per pound" for "limited application as a catalyst in organic synthesis" suggested "a low potential for discharge…."[180] There is no credible reason to conclude that "the economic impact of the designation of hazardous substances" were appropriately considered for designations pursuant to Section 311 but must be ignored for designations pursuant to CERCLA Section 102(a).

b. The Definition of Imminently Hazardous Substances in TSCA Section 7 Expressly Prohibits Consideration of Costs

CERCLA hazardous substances, by definition, include "any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of [TSCA]," which in turn currently defines "imminently hazardous chemical substance or mixture" to mean:

---

[175] 43 Fed. Reg. 10,474, 10,479 (March 13, 1978) (emphasis added).
[176] *Id.*
[177] *See id.* at 10,475.
[178] *Id.*
[179] *Id.* at 10,477.
[180] *Id.*

> a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, ***without consideration of costs or other nonrisk factors***.[181]

It follows that EPA cannot consider costs when assessing whether to take action under TSCA Section 7 regarding a substance, an express prohibition conspicuously absent from CERCLA Section 102(a).

However, costs *were* relevant under TSCA Section 7 as it stood in 1980, the year when CERCLA was enacted, which long preceded the Lautenberg amendments of 2016. At that time, TSCA Section 7(f) defined an "imminently hazardous chemical substance or mixture" as one that "present[ed] an imminent and unreasonable risk of serious or widespread injury to health or the environment."[182] "Imminent" was further defined as "likely to result in injury to health or the environment before a final rule under section 6 [now 42 U.S.C. § 2605] of this title can protect against such risk."[183] Section 2605 was (and still is) the mechanism by which EPA can take action against substances posing "unreasonable risk." Thus, in 1980, for EPA to issue a rule concluding that a substance presented "unreasonable risk," EPA had to consider "the reasonably ascertainable economic consequences of the rule."[184] Therefore, CERCLA Section 102(a) should be read in a similar manner as the contemporaneously enacted provision, that EPA must consider the economic consequences of the rule when determining a substance is hazardous.

c. At a Minimum, CERCLA Section 102(a) Does Not Preclude EPA From Considering Costs

As we have explained, Section 102(a) *requires* the consideration of costs in designating a substance as hazardous under that provision. But we respectfully submit in the alternative that, at a minimum, EPA's assertion that it is forbidden from considering costs under CERCLA Section 102(a) is clearly erroneous and unreasonable. At the very least, EPA possesses discretion to consider costs under Section 102(a), as there is no textual indication that Congress precluded consideration of cost. It would be arbitrary and capricious for EPA to finalize such a designation without providing a rational explanation of how and why it exercised its discretion to reject cost consideration when courts have recognized repeatedly that cost is almost always a fundamental consideration in regulation. That is particularly the case where, as here, cost is a highly relevant and important factor in deciding whether it is "appropriate" to list PFOA and PFOS as hazardous substances, given the likely far-reaching legal and economic consequences, and now that these comments have raised the issue.[185]

---

[181] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. Law No. 114-182 § 7(f), 130 Stat. 470 (June 22, 2016) (codified as amended at 15 U.S.C. § 2606(f) (2020) (emphasis added).
[182] Toxic Substances Control Act, Pub. Law No. 94-469, § 7(f), 90 Stat. 2027 (Oct. 11, 1976) (codified at 15 U.S.C. § 2606(f) (1976)).
[183] *Id.*
[184] *Id.*, § 6(c)(1)(D), 90 Stat. 2022 (Oct. 11, 1976) (codified at 15 U.S.C. § 2605(c)(1)(D) (1976)).
[185] *See, e.g., Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016).

D. EPA's Economic Assessment Is Grossly Inadequate

As discussed earlier in these comments, EPA has taken the position that costs do not need to be considered when designating chemicals as CERCLA hazardous substances. While OMB has designated this rulemaking to be an economically significant action, EPA has not provided a complete regulatory impact analysis and instead has provided only an "Economic Assessment" of potential costs.[186] For a regulation of this importance, significance, and size, this is unacceptable and not consistent with EOs 12866 and 13563 and Circular A-4. EPA's requests for comment on the Economic Assessment do not negate the need for a far more robust analysis. In fact, comments that EPA receives on the proposed rule should be used to inform a proper RIA. Once EPA receives these comments, it should develop a complete RIA that is sufficient to show how the benefits of this rule outweigh the significant costs. This analysis should be released for public comment, along with a revised proposal that takes its findings into account. If the costs were appropriately considered, as discussed below, EPA would find that the decision to designate PFOA and PFOS as hazardous substances is not justified, especially as the outcomes of reduced exposure and accelerated cleanup can be achieved with alternative, less costly means.

1. A Robust Impact Analysis Can and Should Be Developed by EPA

EPA acknowledges that, if finalized, this regulation would indeed lead to increases in the number of CERCLA response actions and that the response costs are more likely to be borne by responsible parties. Yet EPA has taken a position that the uncertainties are too great to quantify, making quantitative estimates "impractical." EPA has provided only a minimal break-even analysis that solely considers the cost of reporting a release to EPA, when considering the impacts on small entities. EPA states that "the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage."[187]

We disagree with the proposition that the uncertainties are too great to conduct a robust analysis. In fact, experts have conducted such an analysis; and we provided it to EPA on June 8, 2022.[188] This analysis, *PFOS and PFOA Private Cleanup Costs at Non-Federal Superfund Sites* (referred to as the Cleanup Cost Analysis),[189] estimates that the costs of cleanup for potentially responsible parties (PRP) could total over ***$17.4 billion dollars*** for existing non-federal national priority sites alone.[190] Annualized private party cleanup costs at existing non-federal sites could

---

[186] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances*, EPA-HQ-OLEM-2019-0341-0035.
[187] 87 Fed. Reg. at 54442.
[188] This analysis, *PFOS and PFOA Private Cleanup Costs at Superfund Sites* was provided to EPA on June 8, 2022, and was also submitted to the regulations.gov docket EPA–HQ–OLEM–2019-0341 on Nov 7, 2022.
[189] The analysis, conducted by experts and prepared for the US Chamber of Commerce, is available at https://www.uschamber.com/environment/pfos-and-pfoa-private-cleanup-costs-at-non-federal-superfund-sites.
[190] Mean estimates for existing NPL sites alone are present value $17.4 billion (90 percent prediction interval equaling $10 billion to $27.2 billion) using a 3 percent discount rate and $9.8 billion (90 percent prediction interval equaling $5.9 billion to $15 billion) using a 7 percent discount rate.

cost $700-$900 million annually.[191] Despite any existing uncertainties, which are qualitatively and quantitatively discussed in the Cleanup Cost Analysis, these costs are simply too large for EPA to ignore.

Further, the DoD's ongoing remediation work provides example cost data that EPA could use to build estimates.[192] Recognizing that private parties are not the only parties impacted by this proposal, EPA should conduct additional economic modelling for federal facilities, municipalities responsible for community water systems, landfills, publicly owned treatment works, and potential state and local brownfield sites. While there are uncertainties in the Cleanup Cost Analysis, and there will be uncertainties in the additional analyses, none of these uncertainties are so great that they should preclude additional analysis. In fact, EPA has acknowledged cleanup cost uncertainties in the past and has still estimated these costs.[193]

2. EOs 12866 and 13563 and OMB Circular A-4 Require a Regulatory Impact Analysis

EOs 12866 and 13563 together establish the requirement that economically significant regulatory actions must be supported by a RIA that includes an assessment of the benefits and costs anticipated from the regulatory action, quantified to the extent feasible, as well as a similar assessment and quantification for identified potential alternatives.[194] EO 13563 further requires that these assessments "use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible."[195] The best available technique for quantifying the benefits of EPA regulations that are directed toward reducing risks is risk assessment. To implement these directives, agencies are instructed to follow OMB Circular A-4, which describes the elements that must be in the regulatory impact analysis of an economically significant regulation.[196] EPA's proposed rule and the associated Economic Assessment do not meet the most basic requirements of a regulatory impact analysis as required by EOs 12866 and 13563 and Circular A-4.

---

[191] *See* EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid as Hazardous Substances*, EPA-HQ-OLEM-2019-0341-0035, at 4.

[192] *See* 217-2019 Remediation Market Survey (Sept. 7, 2022): https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0201.

[193] For example, EPA estimated the cost of cleanup at 456 non-federal NPL sites comprising 1,073 operable units (OUs) with planned remedial actions at between $15.5 and $23.3 billion in 2003 dollars (*see* EPA Office of Solid Waste and Emergency Response, Cleaning Up the Nation's Waste Sites: Markets and Technology Trends: 2004 Edition, EPA 542-R-04-015. 2005). In the same study, EPA uses a similar approach to the Chamber's model to project future CERCLA cleanup costs and derives a range from $23 billion to $50 billion. The study makes key assumptions in the absence of available data, for example, "[i]t was assumed that 50 percent of sites with RD underway have already incurred the RD costs, 50 percent of sites with study underway already have incurred RI/FS costs, and 45 percent of all sites will require LTRA."

[194] *See* EO 12866, § 6(a)(3)(C); EO 13565, § 1(b).

[195] *See* EO 13565, § 1(c). As then OIRA Administrator Cass Sunstein put it, EO 13563 "made an unprecedented commitment to quantification of both costs and benefits." Cass R. Sunstein, "The Stunning Triumph of Cost-Benefit Analysis, Bloomberg Opinion, Sept. 12, 2012. https://www.bloomberg.com/opinion/articles/2012-09-12/the-stunning-triumph-of-cost-benefit-analysis.

[196] OMB Circular A-4 is available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

First, Circular A-4, consistent with EO 12866, requires a statement of need for the regulatory action. This statement should describe the problem that the agency seeks to address. In the Economic Assessment, while EPA has a section entitled "Need for Regulatory Action," EPA does not describe any problem or problems that need fixing.[197] EPA does state that the action would "further CERCLA's primary goal of protecting public health and welfare," but this is not a problem. EPA has not explained why CERCLA, as it currently exists, is not protecting public health and welfare. EPA notes that the designations of PFOA and PFOS as hazardous substances would improve information quality and improve our understanding of PFOA and PFOS releases. However, there is no discussion of a problem that exists due to poor quality information, nor is there a discussion of problems caused by an information insufficiency. The other actions proposed by EPA's Strategic Roadmap do not obviously require designation under CERCLA to achieve the key outcomes. Without identifying a problem, there is no justification for the proposed PFOA and PFOS designations.

Second, Circular A-4, consistent with EO 12866, requires an examination of alternative approaches that the agency considered. Neither the proposed rule nor the Economic Assessment provide any discussion of alternatives that EPA considered. The lack of consideration of even one viable alternative is an egregious error that must be corrected.

Third, Circular A-4, consistent with EOs 12866 and 13563, requires an evaluation of the benefits and costs, quantitative and qualitative, of the proposed action and the main alternatives identified by the analysis. Unfortunately, EPA quantifies only reporting costs and ignores the reasonably foreseeable and predominant quantifiable cleanup costs that would be associated with designating PFOA and PFOS as hazardous substances. Not only does EPA ignore costs to private parties, but it also ignores costs to states, tribes, municipalities, federal facilities, publicly owned treatment works, and landfills. Arguing that most impacts are "indirect effects" is not compelling, as Circular A-4 makes clear that the economic analysis "should look beyond the direct benefits and direct costs" of the rulemaking. Similarly, EPA's arguments that the information is too uncertain also fall flat. Uncertainty is not an acceptable excuse for providing a subpar analysis that ignores the costliest aspects of the proposal. Circular A-4 provides agencies with many options for quantitatively treating uncertainty, including but not limited to sensitivity analyses and probabilistic analyses. Finally, as we have noted previously, as no alternatives are presented, there is no analysis of alternatives.

3. EPA Ignores Indirect Costs of the Listing Decision Even as it Promotes the Potential Indirect Benefits Associated With Additional Site Cleanup

EPA's Economic Assessment estimates only the costs associated with reporting activity. All costs related to potential increases in response activities and increases in the speed of response activities are only qualitatively described. EPA refers to these costs as indirect costs. However, when EPA discusses the benefits of the proposed rule, all the reported benefits related

---

[197] EPA's *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (August 2022) at 23, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.

to health protection stem from these "indirect" effects.[198] This disconnect is particularly noticeable in Section VI (Effect of the Designation) of the proposed rule preamble. When discussing the effect of the designations in this section, EPA makes no mention of increases in response activities and the increases in the speed of response. EPA cannot have it both ways. It cannot, and should not, tout the alleged health benefits of a proposal and then simply ignore their costs. The costs associated with conducting response activities, including the significant costs associated with complex litigation that frequently occurs under CERCLA, is a direct impact of designating substances as CERCLA hazardous substances and must be considered in a regulatory impact analysis.

EPA states that "the multiple, contingent, discretionary and site-specific steps between designation of a hazardous substance and the incurrence of cleanup costs contribute to the inability to quantify costs at the designation stage."[199] This is not convincing. These costs are reasonably foreseeable, ascertainable, and capable of being estimated. As noted above, external experts were able to conduct such an analysis for costs to private parties. EPA has sufficient data from which they can extrapolate and conduct a bounding or sensitivity analysis. Indeed, the proposed rule preamble describes the available data on PFOA and PFOS prevalence, which EPA could easily use as a starting point for extrapolations to inform predictions of new sites that might be designated or additional sites that may require reopening for remediation. Similarly, EPA has a wealth of information to inform the frequency at which sites are placed on the NPL; data also exist to inform the costs of final cleanup decisions, as memorialized in public Records of Decisions (ROD). While these analyses may not be perfect, they would be far superior to simply ignoring costs which are an inevitable and direct result of the proposed rule.

4. EPA's Projected Costs Are Significantly Underestimated

As noted above, in the Economic Assessment provided by EPA, only the reporting costs are quantified. EPA claims that other costs are indirect and/or too uncertain to be quantified. Yet these costs are neither indirect nor too uncertain to be quantified.

Regarding indirect costs, EPA's Guidelines for Preparing Economic Analyses (2010) states: "Indirect costs are the costs incurred in related markets or experienced by consumers or government agencies not under the direct scope of the regulation. These indirect costs are usually transmitted through changes in the prices of the goods or services produced in the regulated sector."[200] Consistent with the direct liabilities that come with a CERCLA designation, impacts to the public, governments (federal, state, local, and tribal), municipalities, publicly owned treatment works, and landfills must be considered by EPA.[201] As discussed above, our external

---

[198] See 87 Fed. Reg. at 54,418 ("A faster pace of cleanups would provide public health protection for affected communities sooner and could reduce the cost of individual cleanups (generally, the sooner contamination is addressed, the less it spreads and the smaller the area that needs to be cleaned).").
[199] 87 Fed Reg. at 54442.
[200] EPA's Guidelines for Preparing Economic Analyses are available at: https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analyses.
[201] CERCLA Section 107, 42 U.S.C. § 9607, in discussing liability, clearly defines persons covered by the statute and the direct coverage is quite inclusive:

> **(a) Covered persons; scope; recoverable costs and damages; interest rate; "comparable maturity" date**

analysis puts a subset of these costs at over ***$17.4 billion*** for existing non-federal national priority sites. This does not include federal, state, local, and tribal sites. It also does not include the costs related to reopening existing sites or adding additional sites to the NPL or costs due to disruptions at many ongoing remediation sites.

EPA's quantified cost upper end value of $370,000 is simply not representative of the direct liabilities that come with a PFOA and PFOS CERCLA designation, which are not only foreseeable but EPA's intended end goal of this rulemaking. EPA's qualitative discussion of direct costs is also insufficient, as it covers only costs associated with CERCLA Section 120(h) notifications. EPA's discussion of indirect qualitative costs is also insufficient. EPA must consider not only the costs associated with site cleanups, investigations, and associated litigation, but also the direct impacts that this rulemaking will have on slowing the speed of ongoing state cleanups and brownfield remediations. Agricultural impacts (due to impacts on biosolids) should also be considered, along with the increased waste management challenges that will be created by the soil that could be deemed to be a hazardous substance.

EPA also fails to consider the cost of "regulatory familiarization" in the economic analysis. Regulatory familiarization costs account for the value of time and effort that every potentially affected individual or business must undertake to determine if the regulation applies to their situation or not, and how their activities must adapt to comply. It is often the largest component of the initial year economic cost of any regulation. When an agency takes careful notice of the regulatory familiarization issue, it writes the rulemaking notice and accompanying public communications in a manner that makes it immediately clear to unaffected persons and entities that the new rule does not apply to them. This attention to communication detail minimizes the familiarization time. Neglecting this analysis can unintentionally impose an enormous familiarization cost burden on the general public. In this proposal, EPA has assumed

---

Notwithstanding any other provision or rule of law, and subject only to the defenses set forth in subsection (b) of this section—
(1) the owner and operator of a vessel or a facility,
(2) any person who at the time of disposal of any hazardous substance owned or operated any facility at which such hazardous substances were disposed of,
(3) any person who by contract, agreement, or otherwise arranged for disposal or treatment, or arranged with a transporter for transport for disposal or treatment, of hazardous substances owned or possessed by such person, by any other party or entity, at any facility or incineration vessel owned or operated by another party or entity and containing such hazardous substances, and
(4) any person who accepts or accepted any hazardous substances for transport to disposal or treatment facilities, incineration vessels or sites selected by such person, from which there is a release, or a threatened release which causes the incurrence of response costs, of a hazardous substance, shall be liable for—
(A) all costs of removal or remedial action incurred by the United States Government or a State or an Indian tribe not inconsistent with the national contingency plan;
(B) any other necessary costs of response incurred by any other person consistent with the national contingency plan;
(C) damages for injury to, destruction of, or loss of natural resources, including the reasonable costs of assessing such injury, destruction, or loss resulting from such a release; and
(D) the costs of any health assessment or health effects study carried out under section 9604(i) of this title.

that there will be no incremental costs associated with rule familiarization.[202] This assumption is flawed.

As proposed, this rule could potentially impact 261,477,000 persons and 7.96 million business establishments.[203] Under the heading "Does this rule apply to me?" EPA states "any person … as soon as they have knowledge of any release … at or above the reportable quantity must immediately report such releases."[204] This imposes on every person a duty to be aware and to be alert. The initial year familiarization cost will most likely exceed the $100 million threshold of EO 12866's designation of an "economically significant" rulemaking and the $150 million threshold for designation of a "major" rule under the Congressional Review Act.[205]

The agency should withdraw the proposed rule, undertake the data collection and communication strategy work that needs to be done before issuing any proposed rule, and realistically consider familiarization cost burdens in its presentation of any future proposals. It should also consider ways in which individuals and business establishments could be exempted from the proposal in order to decrease the cost burdens of rule familiarization.

E. The Proposed Rule Does Not Appropriately Analyze Costs to Small Business and Creates Unfunded Mandates

EPA inappropriately certifies under the Regulatory Flexibility Act (RFA) that this proposed rule would not have a significant economic impact on a substantial number of small entities, and thus that it does not need to complete a regulatory flexibility analysis or initiate the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process.[206] EPA also mischaracterizes the rule as not containing an unfunded mandate of $100 million or more as described in the Unfunded Mandates Reform Act (UMRA) and does not significantly or uniquely affect small governments.[207] EPA's basis for these certifications is on its calculation of the nominal costs of reporting releases only. EPA does not consider the significant costs that a final rule would impose on small businesses as well as state, local, and tribal governments in

---

[202] EPA, *Economic Assessment of the Potential Costs and Other Impacts of the Proposed Rulemaking to Designate Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as Hazardous Substances* (Aug. 2022) at 40, https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0034.

[203] 261,477,000 is estimated U.S. civilian non-institutional population age 16 and older in 2021 (annual average) as reported by Bureau of Labor Statistics at https://www.bls.gov/news.release/empsit.a.htm; 7.96 million is estimated number of U.S. private business establishments in 2019 (latest available) published by U.S. Census at https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html.

[204] 87 Fed. Reg. at 54,416.

[205] The dollar values are simple multiplications of the population and business establishment totals by the hourly wage ($32.46 hourly wage for individuals per BLS at https://www.bls.gov/news.release/empsit.t19.htm and $59.31 per BLS hourly wage for business establishment managers at https://www.bls.gov/Oes/current/oes110000.htm. Using a *de minimis* one hour time frame to read EPA's public information materials, the cost to individual citizens would be $8.5 billion, and the cost to business establishments would be $466.1 million. Because the actual time burdens to read and understand the EPA public information materials and the regulatory text are likely much greater than the one hour parameters used in these hypothetical examples, and because the opportunity cost time values may also be greater, the actual familiarization cost burden of the proposed rule as published is likely much more than the $8.95 billion sum of the calculations shown above.

[206] 87 Fed. Reg. at 54,440.

[207] *Id*.

Without an explanation of why it did not consider these costs, EPA fails to satisfy its obligations under the UMRA to assess whether the proposed rule may result in the expenditure of funds by SLTG in the aggregate, or by the private sector, of $100 million or more in any one year. If it had, the likely result would be that EPA is required under the UMRA to consult with SLTGs and prepare a regulatory impact statement. EPA would also be required to consider regulatory alternatives and select the least costly, least burdensome, or most cost-effective option that achieves the objectives of the rule or explain why it did not make such a choice.

F. EPA Makes No Showing That its Designations Pursuant to CERCLA Section 102(a) Are Entitled to Retroactive Treatment

CERCLA has also been interpreted to create retroactive liability. The Act has been construed broadly in order to give effect to its purpose,[220] and even though retroactivity is not set out expressly in CERCLA's statutory text, every court of appeals to have considered the question has concluded that Congress intended CERCLA to apply retroactively to current and former owners, operators, arrangers, and transporters.[221] Nonetheless, it is well settled that federal laws and regulations are not construed to have retroactive effect unless there is a clear statement in the statute that indicates retroactive application.[222]

EPA's justification for designating PFOA and PFOS as hazardous substances fails to even address how EPA's exercise of the authority delegated by Congress in CERCLA Section 102(a) should be afforded retroactive effect. Congress did not delegate in CERCLA Section 102(a) the power to assign sweeping retroactive liability, which in the case of PFOA and PFOS would subject millions of unexpecting property owners to liability.

1. CERCLA Section 102(a) Does Not Authorize Application of EPA's "Hazardous Substances" Retroactively

The EPA's justification for designating PFOA and PFOS as "hazardous substances" pursuant to CERCLA Section 102(a) makes no attempt to explain why such a designation should enjoy the same retroactive treatment as is provided for other substances that Congress declared to be "hazardous substances" under CERCLA. As the U.S. Supreme Court explained in *Bowen v. Georgetown University Hospital*,

> Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result. By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. Even where some substantial justification for

---

[220] *B.F. Goodrich Co. v. Betkoski*, 99 F.3d 505, 514 (2d Cir. 1996).
[221] *See, e.g., Commonwealth Edison Co. v. United States*, 271 F.3d 1327, 1350-51 (Fed. Cir. 2001); *United States v. Northeastern Pharm. & Chem Co.*, 810 F.2d 726, 734 (8th Cir. 1986); *United States v. Monsanto Co.*, 858 F.2d 160, 174 (4th Cir. 1988); *Franklin County Convention Facilities Auth. v. Am. Premier Underwriters, Inc.*, 240 F.3d 534, 551-52 (6th Cir. 2001).
[222] *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Landgraf v. USI Film Prods.*, 511 U.S. 244, 270 (1994).